IS THE U.S. DEPARTMENT OF VETERANS AFFAIRS MEETING THE PHARMACEUTICAL NEEDS OF VETERANS?

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH

OF THE

COMMITTEE ON VETERANS' AFFAIRS
U.S. HOUSE OF REPRESENTATIVES

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IS THE U.S. DEPARTMENT OF VETERANS AFFAIRS MEETING THE PHARMACEUTICAL NEEDS OF VETERANS?

TUESDAY, SEPTEMBER 22, 2009

U.S. HOUSE OF REPRESENTATIVES,
COMMITTEE ON VETERANS' AFFAIRS,
SUBCOMMITTEE ON HEALTH,
Washington, DC.

The Subcommittee met, pursuant to notice, at 2:02 p.m., in Room 334, Cannon House Office Building, Hon. Michael H. Michaud [Chairman of the Subcommittee] presiding.

Present: Representatives Michaud, Snyder, Teague, Halverson, and Perriello.

OPENING STATEMENT OF CHAIRMAN MICHAUD

Mr. MICHAUD. I would like to call the Subcommittee on Health now to order, and I would like to thank everyone for coming.

The goal of today's hearing is to determine whether the U.S. Department of Veterans Affairs (VA) is meeting the pharmaceutical needs of our veterans. We are conducting this hearing because of the concerns that we have heard from our veterans about proper access to nonformulary prescriptions, concerns about adverse drug interaction and patient safety, and recent reports by the Office of Inspector General (OIG) citing the need to better manage certain aspects of the VA's pharmacy benefit program.

When properly designed and implemented, formularies can provide drug therapy that is rational, clinically appropriate, safe and cost-effective. However, patients' care may be compromised if the formulary system is not developed and administered so that individuals can access drugs that they need. I have heard from veterans who have voiced their frustration with the VA National Formulary as being too restrictive to the point that accessing appropriate drugs is a barrier.

Some veterans have pointed to a flawed subjective system by securing nonformulary drugs. For example, a veteran who was denied access to a nonformulary drug at one VA medical center may be approved by another medical center, which suggests that the decision may not be based entirely on clinical factors.

I also have concerns about patient safety and whether we are doing enough to prevent the adverse drug events. Among the medication errors leading to adverse drug events are missed doses, duplicate therapy, drug-to-drug interaction, inadequate monitoring and preparation errors.

And finally, the recently released audit report from the Office of the Inspector General raised concerns about the VA's management of noncontrolled drugs and Consolidated Mail Outpatient Pharmacy (CMOP) contracts. So we have panels here today of experts to help us explore these issues. And I look forward to hearing from them as well.

And I would now like to recognize Mrs. Halvorson if she has an opening statement she would like to make.

[The prepared statement of Chairman Michaud appears on p. 31.]

OPENING STATEMENT OF HON. DEBORAH L. HALVORSON

Mrs. HALVORSON. Thank you, Mr. Chairman.

I appreciate all of you for being here. This is one of the issues that is probably brought up more and more every time I get together with my veterans, so I appreciate having the opportunity to ask questions.

Many times, people will come to me and say, how come these drugs are covered, and all of a sudden I get a notice saying that this will no longer be covered any more? So, again, I thank the Chairman for putting this together because this is one of those important issues that we need to get to the bottom of and make sure that we take care of our veterans. Our motto here is, if you were there, we care. And we need to make sure that we truly do care and don't just give it lip service

Mr. MICHAUD. Thank you very much, Mrs. Halvorson, and I also want to thank you for your leadership and your advocacy for veterans and their families during your short timeframe so far here as a Member of Congress. So thank you.

I would like to ask the first panel to come up, please.

On our first panel we have Dr. Jack Hoadley; Dr. Frank Lichtenberg; Rick Weidman from the Vietnam Veterans of America (VVA); and William Bullman, who is the Executive Vice President of the National Council on Patient Information and Education.

I would like to thank the four of you for coming forward today to give us your thoughts and to help us deal with this very important issue.

So, without any further adieu, I would like to begin by asking Dr. Hoadley to begin.

STATEMENTS OF JACK HOADLEY, PH.D., RESEARCH PROFESSOR, HEALTH POLICY INSTITUTE, GEORGETOWN UNIVERSITY, WASHINGTON, DC; FRANK R. LICHTENBERG, PH.D., COURTNEY C. BROWN PROFESSOR OF BUSINESS, COLUMBIA UNIVERSITY, NEW YORK, NY, AND RESEARCH ASSOCIATE, NATIONAL BUREAU OF ECONOMIC RESEARCH; RICHARD F. WEIDMAN, EXECUTIVE DIRECTOR FOR POLICY AND GOVERNMENT AFFAIRS, VIETNAM VETERANS OF AMERICA; AND WILLIAM RAY BULLMAN, M.A.M., EXECUTIVE VICE PRESIDENT, NATIONAL COUNCIL ON PATIENT INFORMATION AND EDUCATION, BETHESDA, MD

STATEMENT OF JACK HOADLEY, PH.D.

Dr. HOADLEY. Well, good afternoon, Mr. Chairman, and Members of the Subcommittee.

My name is Jack Hoadley. I am a Research Professor at Georgetown University's Health Policy Institute. And as a long-time analyst of prescription drug issues, I have conducted quite a few different research projects on formularies and other approaches to managing the use of prescription drugs, both in Medicare and Medicaid, in the VA and private-sector health plans. And I appreciate the opportunity to speak to the Subcommittee on these important issues.

In the Congressional debates over the Medicare Part D benefit, the role of the VA National Formulary has been invoked on a regular basis. Some point to it as a source of low prices and an example that the Medicare Program might follow. And others claim that access to drugs is more restrictive in the VA system. And so, my colleagues and I took on a couple of years ago the idea of conducting an objective comparison of the VA National Formulary to the formularies that are used by some of the Medicare Part D plans.

First, just a little bit of background. There is a long history in the VA of using formularies. It really goes back several decades culminating in the process of implementing a national Formulary just a couple of years ago, and it is important to note that the VA National Formulary really functions differently than those in many of the private health plans. The VA is an integrated system. Veterans go to VA facilities to see VA doctors and fill prescriptions at a VA pharmacy; whereas, in the private sector, they go get a prescription, go to the pharmacy, and that is where they find out that a drug is not covered. The VA pharmacy is more of a clinical tool used by physicians rather than an enforcement tool of the plan that is applied at the pharmacy.

So in our analysis we wanted to compare the VA formulary with those used in some of the leading Medicare Part D plans, and we used a sample of about 160 commonly prescribed drugs. This was done in 2007. We wanted to look at the counts of drugs in the VA formulary compared with counts of unrestricted drugs on Medicare formularies, and by "unrestricted," we mean a drug that is not a nonpreferred drug at a higher copay and a drug that does not require any kind of prior authorization or other utilization management restriction.

In the straight count of drugs in the two formularies, we found that of our 160 drugs, the typical Part D plan covered about 104 of those drugs, and the VA covered about 82. The VA was more comparable to the major integrated health system in the Medicare system, Kaiser Permanente, which covered 77 and 79 drugs in 2 of its regions in California.

But the numerical comparison is really not the entire story. There are a couple of differences between how the VA formulary works and the perspective that Medicare plans use in creating their formularies. One is how they treat generic drugs. The VA covers about three-quarters of the generic drugs in our sample on its formulary, whereas most of the Medicare plans list all of them on formulary. And the VA is basically going through and looking at the generic drugs and trying to pick, based on clinical evidence and price, the most appropriate of the generic drugs to be included on the formulary.

By contrast, the Part D plans, because they don't have relationships created with the physicians that are going to prescribe medications, find it easier to simply list all the generic drugs because, otherwise, they are going to spend time with rejections at the pharmacy, make their enrollees unhappy and, in the end, probably go ahead and approve that drug or get somebody to switch to a different drug. And so, as a result, they tend to put all the generic drugs on the list, whereas the VA is making a judgment on clinical evidence and price and then allowing an exceptions process to operate for other drugs.

There are also some program rules in Medicare that make a difference there as well.

But the other part of our analysis was to look at the prescribing and the frequency of prescribing of the drugs not listed on the VA formulary. We took a number of examples, and the one I will mention here today is cholesterol drugs, and that is one of the most commonly prescribed drug classes and one where some of the criticism of the VA formulary has been. And the VA says in their guidelines that a high-potency formulary statin for cholesterol, normally a generic, should be the first line treatment for treating high cholesterol. But the guidance goes on to say that physicians should consider a second line therapy, for example, the nonformulary drug Zetia or a nonformulary statin, such as Lipitor, if particular patient circumstances warrant it.

And this is a guidance that is very consistent with other evidence-based comparative-effectiveness reviews. And we took a look at the prescribing of these nonformulary options, and we found that, in 2006, the VA actually filled 700,000 prescriptions for Lipitor, a nonformulary statin, and 350,000 prescriptions for Zetia that year. And this is actually more utilization than for some of the formulary drugs that treat cholesterol. So, to us, that looked like evidence that where drugs are not listed on the formulary, they really still are very much accessible to beneficiaries.

So, in conclusion, our objective comparison does show that the VA formulary is modestly smaller than that in the typical Medicare plan, although similar to those used by integrated healthcare systems like Kaiser Permanente. But since, as I suggested, formulary size is not the only measure of access to drugs, we think that the

difference in the two systems, the more integrated system where physicians had the ability to prescribe from a formulary that they have worked with and get exceptions made in what seems to us to be a pretty readily done basis, that in the end, the veterans are getting access, good access to drugs through the VA formulary.

So, with that, I will conclude my remarks.

[The prepared statement of Dr. Hoadley appears on p. 31.]

Mr. MICHAUD. Thank you very much, Dr. Hoadley.

Dr. Lichtenberg.

STATEMENT OF FRANK R. LICHTENBERG, PH.D.

Dr. LICHTENBERG. Thank you, Mr. Chairman, and Members of the Subcommittee. I have a PowerPoint which I will refer to.

Research that I and other economists have performed indicates that access to medical innovations, that is new drugs, medical procedures and devices, is one of the most important determinants of longevity and health.

Four years ago, I performed a study that examined access to new drugs under the Pharmacy Benefits Management System of the Veterans Health Administration (VHA). And since 1997, the VA National Formulary has played a key role in that system. And some of the key findings of my report, the full text of which there is a link at the end of my remarks, can be summarized by several graphs.

So, figure one shows the percent of drugs on the 2005 VA National Formulary by decade of Food and Drug Administration (FDA) approval. And I guess the striking thing that we see here is that if we look, for example, at drugs approved by the FDA during the period 2000 to 2005, only 19 percent of those drugs were on the VA National Formulary. And even if we look at so-called priority review drugs, that is drugs that in the FDA's opinion represent significant advances over existing treatment, only a relatively small fraction of these drugs were on the VA National Formulary. However, even if a drug is not on the National Formulary, a VA patient may have access to a drug through the local formulary or through a formulary exception.

And so it is important to look not just on what is on the formulary, as Dr. Hoadley suggested, but at the drugs that are actually being used by VA patients. And as a benchmark, I compare them to non-VA patients. And so, to do this, I used data from a government survey, the Medical Expenditure Panel Survey, where we have data on a large number of prescriptions consumed in both the VA system and non-VA patients. And what I did was compare the average age of drugs used by VA and non-VA patients. I define the age of a drug as how many years ago the active ingredient of the drug was approved by the FDA. In other words, Lipitor was approved by the FDA in 1996, so at this point, it is a 13-year-old drug. And I have found very, I think, compelling evidence that patients that use older drugs on average tend to have worse outcomes than patients using newer drugs.

So what I do in this comparison is compare the age of the drugs used by VA and non-VA patients. And for example, if you look at the right hand bar, what it shows is that 39 percent of drugs used by non-VA patients are older than 15 years, whereas for—I am

sorry are less than 15 years old, whereas the percentage that are less than 15 years old for VA patients is 31 percent. So, in other words, the drugs used in the VA health system during the period 1999 to 2002 were older than the drugs used in the rest of the U.S. healthcare system. And in fact, the age of the drugs was, the relative gap was actually increasing. That is consistent with the hypothesis that implementation of the VA National Formulary beginning in 1997 reduced utilization of new drugs in the VA healthcare system.

But what we presumably all care about is outcomes; is longevity, disability, quality of life and so forth. I have done a number of studies and some other economists have as well about the impact of medical innovation and pharmaceutical innovation in particular on longevity and other health outcomes. And in this paper, I present some new estimates that suggest that the use of older drugs in the VA system may have reduced the life expectancy or mean age of death of VA patients by about 2 months. Now that doesn't sound like a very significant number; however, there is other evidence that suggests that people's willingness to pay, Americans' willingness to pay to extend their lives is quite high, so the per-patient value of that reduction in longevity may exceed $25,000 per person.

I also use demographic data published by the VA to compute the life expectancy of veterans both before and after the National Formulary was implemented. And here the picture is the following, that starting in 1991, from 1991 to 1997, the life expectancy of American veterans increased by about 3 years. However, it stopped increasing after 1997 and maybe even declined a little bit, and that coincides pretty precisely with the implementation of the VA Pharmacy Benefits Management System. So I think that that is evidence that needs to be considered further.

Thank you.

[The prepared statement of Dr. Lichtenberg appears on p. 39.]

Mr. MICHAUD. Thank you very much, Dr. Lichtenberg.

Mr. Weidman.

STATEMENT OF RICHARD F. WEIDMAN

Mr. WEIDMAN. Mr. Chairman, first of all, I want to thank you for your leadership in holding this hearing today.

There really are two levels of issues here on the table. The first is, and the one which our written statement primarily concerns itself with, is access to getting new medications on the formulary to begin with. We believe that it is inappropriate cost management at the cost of proper clinical care. Many drugs are not making it on. That is a clinical decision.

And that process by which things go on is a closed process. In other words, it is not a transparent process. The advocates, the veterans service organizations, the medical societies do not have the opportunity to comment. There is no recipient advisory group that has a chance to have the say for what the veterans and their families have to say about this; what does the medical community in general have to say about this?

Cutting to the chase, what we propose and urge you to consider is moving to introduce legislation that will make the VA formulary

mirror that at U.S. Department of Defense (DoD). The DoD formulary, everything, as soon as it is FDA approved, as soon as practical, which is usually a short period of time, it goes on the DoD formulary or the TRICARE formulary.

The veterans on active duty suddenly shouldn't feel the pinch that those who are no longer on active duty, either because they retired or because of longevity or because they have ended their term of service because they got wounded, should have the access to the full range of drugs that those on active duty should have. That is also incidentally an open and transparent process. It is warned. There are public meetings. There are minutes, and there are a number of recommendations, which actually Secretary Shinseki can take even without such legislation, but we would encourage you to move ahead and to develop comprehensive legislation in association with your friends over at the House Armed Services Committee, who are thoroughly familiar with that process, and move forward to do it.

One of the fallacies of limiting the formulary is that we are saving money. We would argue that it is penny wise and pound foolish. Oftentimes the lack of the proper medication at the proper time because it wasn't on the formulary leads to all kinds of healthcare impact that results in sicker patients and episodes that did not have to happen.

I will use, just as one example, diabetes. And you may recall that a patient advocate leadership summit last year with veterans service organizations came together in Washington, and we focused on four diseases. One of those was diabetes, and what stunned all of us in the veterans service organization community is that, in fiscal year 2006, two-thirds of the cost of care for diabetes went into acute inpatient stays.

Let me say that again: Two-thirds of the total cost of treating the 1.2 million diabetics who go to the VA for their healthcare was in inpatient treatment services. What that means is, when you have to put somebody in the hospital who is under a physician's care who has diabetes is that you failed. You have failed big time.

And as a result of that, that is very expensive. It causes secondary conditions, which leads to amputations of limbs. It causes all kinds of secondary conditions which are then themselves service-connected compensable. This is particularly true for Vietnam veterans, where those of us who served in Vietnam where diabetes is in fact service-connected presumptive. That is one level.

I don't have much time to comment on the second level except to say that the overall management, people are generally happy with the timeliness of the medications, assuming that they can get the medications that they need off of the formulary. But by changing what goes on to the formulary, you have competent people to manage the system.

But I cannot stress too strongly that while they say that unions sometimes mirror the worst excesses of the business industry in which they organize, in this case, the VA has mirrored the worst in past decade or 15 years of the pharmaceutical industry, which lost its way for a time and seems to be finding its way again, where they forgot they were in the health business. That is the business they are in, in helping people get well, stay well as long as pos-

sible, and they are not in the cost-containment or selling the most widgets or having the highest cost reduction on the case of the government side or their cost margin and profit margin on the case of the private industry side.

Mr. Chairman, once again, thank you very much for holding this hearing today. And I would be happy to answer any questions sir.

[The prepared statement of Mr. Weidman appears on p. 42.]

Mr. MICHAUD. Thank you very much.

Mr. Bullman.

STATEMENT OF WILLIAM RAY BULLMAN, M.A.M.

Mr. BULLMAN. Good afternoon, Mr. Chairman, Members of the Subcommittee.

I am Ray Bullman, Executive Vice President of the National Council on Patient Information and Education, NCPIE. I have been asked to testify this afternoon relative to three areas: one, the broad range of patient medication safety issues; two, best practices or innovative means that our coalition members employ to enhance medication safety; and three, how NCPIE as a multi-stakeholder coalition meets its mission to stimulate and improve communication of information on appropriate use of medicines to consumers and healthcare professionals.

I would note at the outset that while NCPIE does not focus specifically on formulary issues, we recognize the impact that formulary decision-making plays downstream on patient and healthcare provider communication, informed decision-making about therapy choice, and what medication is prescribed and ultimately to what extent patients effectively self-manage their medication therapy. NCPIE is, therefore, pleased to help support the work of the Subcommittee.

In my written testimony, I have outlined specific safety issues deriving or arising from each of nearly a dozen medication-use and safety issues that impact medication safety. If I may, I would address just one of these equally important and much-entwined medication safety issues as a way of demonstrating the magnitude of the problem and the vital role that VA pharmacists can play in addressing it. That issue is medication nonadherence, which just recently was estimated to cost the U.S. economy over $290 billion annually or 13 percent of total healthcare expenditures.

I hold out medication nonadherence by way of example because it is so multifactoral in its cause and so emblematic of a wide range of medication-use problems patients experience beyond simply not being able or willing to follow prescribers' directions on the vial, for example. For example, it embodies the challenges of polypharmacy.

During the last decade, the number of medicines available to treat many chronic diseases has increased. NCPIE supports and promotes efforts to conduct medication reconciliation that results in a more complete medication record for providers and pharmacists, and applauds the Joint Commission for its leadership and its members working to establish effective medication reconciliation within the hospital setting and back out to patients' healthcare providers in the ambulatory care setting.

Medication nonadherence also brings to the fore issues like the complexity of the medication regimen, multiple prescribers who do

not communicate amongst themselves, concerns about side effects and concerns about costs, for example.

In my written testimony, I have described several best practices programs or policy recommendations that several of the NCPIE member organizations, mostly pharmacy and patient-safety groups, advance to enhance medication and patient safety. These range from collaboratively developed medication-therapy-management guidelines for pharmacists such as the American Pharmacists Association and the National Association of Chain Drugs Stores has developed and produced, for example, or the establishment of and roles and responsibilities of the Medication Safety Officer within the hospital setting, or online medication safety self-assessment tools designed to help health organizations assess the medication safety practices in their respective institutions.

Area three is how NCPIE works to meet its mission through its broad membership. NCPIE works to meet its mission through both in-house development and implementation of educational products, programs and services, and through convening or participating in collaborative programs with both member and nonmember groups. Each of the following examples enables NCPIE to promote and disseminate a wide range of educational resources, including educational videos, medication wallet cards, personal medication lists, and key questions that each consumer and healthcare provider should discuss before any medication therapy is initiated.

We also work through creation of a dedicated reoccurring event, "Talk About Prescriptions" Month, each October, the purpose of which is to enable high-quality medicine communication to have its rightful place on the public health landscape and agenda. This October will mark the 24th annual "Talk About Prescriptions" Month. We also work through key external partnerships with our "Be MedWise: Safe Use of Over-the-Counter Medicines Campaign." We have collaborated and partnered with the Food and Drug Administration, the American Pharmacists Association and the Surgeon General's Office, then Dr. Richard Carmona, to expand the scope of the campaign.

NCPIE also licenses content, for example, for its "Be MedWise" campaign to two State universities through their cooperative extension programs for Be MedWise Tennessee, a statewide initiative, and Be MedWise Arkansas.

We also work through convening expert project advisory teams. Our most recent product is "Maximizing Your Role As a Teen Influencer: What You Can Do to Help Prevent Prescription Drug Abuse." We worked with 14 national expert organizations on developing that program.

And last, we work with external coalitions. For example, we are a member of the National Coordinating Council for Medication Reporting and Prevention and the Safe Medication Disposal for ME, or Maine, program; we are a member of that advisory team.

I would thank the Subcommittee for inviting NCPIE to testify, and I look forward to answering any questions you may have. Thank you very much.

[The prepared statement of Mr. Bullman appears on p. 46.]

Mr. MICHAUD. Thank you very much, each of you, for your testimony, and I do have a few questions.

I will start off with Dr. Hoadley. The Institute of Medicine (IOM), over a decade ago, came out with a report that found VA had a responsive process in place for assuring access to medically necessary drugs to the formulary. Do you believe that the Institute of Medicine's original findings still apply today? And if not, do you think they should be updated?

Also, could you comment on Mr. Weidman's suggestion that the VA should be very similar to what the DoD has in place when they deal with the formulary?

Dr. HOADLEY. To take the second question first, I have not taken a look at the DoD formulary in my own research, so I can't speak directly to that.

One question would need be raised in looking at how the DoD formulary works. To the extent that the TRICARE program is like the way Medicare drug program works and operates through a number of private health plans, it is a somewhat different environment than the VA system, which as an integrated health system. That means a formulary really works differently.

I think that is an important point to emphasize. In an integrated system, the idea, if things are working correctly, is that the physicians have collectively bought into the formulary. They have some role in helping to plan and have input into the formulary, and then they are really committing themselves to prescribing from the formulary where possible and then getting exceptions where it is needed for particular patient circumstances. So that is really part of the question to ask.

In terms of your first question on the IOM study, I think my findings are generally consistent with what that study found several years ago, that the VA system does seem to be operating well; the formulary does seem to be serving the needs of veterans. And our findings of drugs that are on the formulary itself and the relative ease with which exceptions seem to be provided given the numbers of prescriptions for nonformulary drugs that we identified seem to support that.

I know at the time of the IOM study, there were a couple of different surveys done of physicians to ask physicians whether they felt they were able to prescribe adequately from the formulary and to get exceptions where needed. At the time, those surveys generally supported that idea. It could always be helpful to go back and conduct such surveys again to see whether physicians in the VA system still feel they are able to get the exceptions when needed and are able to prescribe well from the formulary.

Mr. MICHAUD. Thank you.

Dr. Lichtenberg, in addition to your concern with the older drugs on the VA formulary, do you believe that the current size of the VA formulary is adequate? Should it be updated to include newer drugs?

Dr. LICHTENBERG. To be quite honest, I have not looked at the current state of the VA formulary, so I couldn't really comment on that.

But I would say it is my impression that there have not been dramatic changes in policy since I did the study in 2005, and therefore there is, for example, a policy that no drug will be listed, only under extraordinary circumstances, perhaps human immuno-

deficiency virus drugs, within, until 1 year after it has been approved by the FDA. So there is a general predisposition against listing new drugs on the formulary. I think that that policy continues and that it is potentially having adverse effects on the healthcare of veterans.

Mr. MICHAUD. Are you familiar at all with the DoD process in getting drugs on the formulary?

Dr. LICHTENBERG. I am afraid that I am not.

Mr. MICHAUD. Thank you.

Mr. Weidman, you brought up a very good suggestion about looking at the DoD formulary and the process that they go through, and reading your testimony I assume that that process is more transparent than the VA process.

That being said, can you tell me what process a veteran or someone would have to go through to get a physician to prescribe a drug that is not on the formulary? Is it a cumbersome process? Have you heard of any complaints about counselors getting supervised or reprimanded by the supervisor if they go off the formulary?

Mr. WEIDMAN. The answer is, it is extraordinarily difficult. It takes a lot of time. It is a cumbersome process and deliberately so. And even incidentally for some expensive drugs that are on the formulary, they will put them on fourth or fifth screen back and make it difficult for people to access the more expensive drugs at some stations. And nobody has really looked at that, and nobody is policing that.

The issue over trying to get medications that are not on the formulary, that is always VA's rejoinder, is that the formulary is fine because people can get anything that is not on the formulary when it is clinically indicated.

But that is just flat not true as a practical matter. We hear from clinicians all the time both in physiological and in neuropsychiatry that if they take things and make recommendations for drugs that are not on the formulary, not only does it take an enormous amount of time when they are under pressure to see patients, face-to-face encounters with patients, but also they get spoken to. They get spoken to enough times, and they don't, and they are down the road; it is as simple as that.

And it is clearly a conscious policy. Part of the problem is the way in which we have misapplied comparative effectiveness within the VA so that it becomes a race to the bottom, so that the pharmacy is measured about cost avoidance below the national mean average. Well, what happens if you have all 152 stations doing that, of trying to get below the mean average? Well, it continues to go down. And that is the wrong measure. What chief pharmacists and all pharmacists ought to be measured against is how much did you contribute to the overall wellness of the individual patients at this medical center and avoid inpatient stays and keep the patient more healthy and contributing for those of working age to the overall economy. Those should be the questions we should be asking. And it is possible to develop metrics that way. People are going to do what you measure them on. It is as simple as that. And we need to change the way in which we think about pharmacy at the VA, and we need to change the way in which VA measures it internally.

And one last thing, if I may mention on that issue, you asked about the IOM. We do need to revisit the IOM because what the IOM said is, there are no good metrics inside the VA to measure what is going on and to analyze it from the outside. And that is still the case today. And if they have measurements, they are refusing to share it with anybody. And once again, stuff that happens in the back room is where bad stuff happens. We are a democracy. This should be done out in the sunshine. And the way in which the DoD process happens is it is a totally public process with an advisory committee and with minutes and people can attend, and it is warned in the Federal Register, et cetera, et cetera. And we need the same kind of process with the VA and that a lot of the problems, we believe, if we adopt the DoD policy on formulary will come to, will go away.

Just one last thing. The theory is that clinical stuff is taken into account at the VA. And with all due respect, the way you mentioned before about clinical evidence and it is collaborative decision of the doctors; well, it is not. It is not. The green-eyed boys always trump. The cost always trumps clinical evidence when it comes to putting things on the VA formulary. So that, even when they are looking through the molecular entity process that they have set up, they can go all the way through that and have strong evidence about cost effectiveness as well as the efficacy of the drug, and then the formulary people, the pharmacy people can still veto it just on the basis of cost and impact on the pharmacy. And this is just not right.

Clinical decisions need to predominate throughout the VA. And if we can't do that, then we are certainly not delivering care second to none. One could argue that then it is care second to all. And that is not the way we should be doing business, and frankly, we have so many wonderful clinicians in the VA, if we can fix the system and let them do their job, we will be care second to none.

Mr. MICHAUD. Thank you very much.

Mr. Weidman, you mentioned the DoD formulary. Since there are more drugs on that formulary than on the VA formulary, have you heard complaints where a servicemember may be using a certain drug that is on the DoD formulary, moves to the VA system, and is no longer able to get that medication?

Mr. WEIDMAN. I have, and also our friends in modern warfare have told me many of those problems as well where people are kind of stunned because, particularly those that come out of Walter Reed, and Walter Reed still has some problems particularly with medical boards and with case management, but it is overall, you know, a fabulous facility, and all of a sudden, bang, they hit the VA system back home in Michigan or Togus or wherever the case may be, and one of the things they hit is the formulary and difficulties, particularly those who have traumatic brain injury (TBI) and seizures. It is very difficult because a lot of those things are not on the formulary, and therefore, their doctors have to go through circumlocutions. They can get it. Their VA doctors are willing to do it, but it is not right that they should jump through hoops.

Those are the kinds of things that should automatically be presumed to be in, and we need to balance the system so we go back to clinical input at every step of the way and achieve a balance be-

tween cost and best clinical care, and currently, we would argue that cost is trumped all the way down the line on this one.

Mr. MICHAUD. Thank you very much.

Mrs. Halvorson.

Mrs. HALVORSON. Thank you, Mr. Chairman, and thank you all for being here.

I have got several questions, and I guess I am not sure where to start.

First of all, again, the IOM study, actually is in quotes, where it says that it has a responsive process in place where assuring access to medically necessary prescription drugs. So—oh, for exceptions to the formulary. So that actually is said in the study that was done almost a decade ago, so obviously we need to look. How do you feel about the fact that that is actually written in this IOM study that obviously needs to be taken a look at?

Now, Mr. Weidman, you have said that we need to take a look at that again. So it is one thing to say we need to take a look at it and another thing to do it. So what would you suggest, because you say most of these things are done behind closed doors, how do you profess that we take this out and do it in the open? Do another study first? What would be your idea?

Mr. WEIDMAN. Well, the IOM study, by the time you get it going is going to take a year and a half, and I would suggest that many of the things in the recommendation section of my statement, Congresswoman, are things that the Secretary could start doing right now to open up this process while the Congress considers whether or not to change the statute and mirror that which is used by DoD and TRICARE and TRICARE For Life, that mandating or just requesting with this Secretary, I think you can just request to him that he contract with the IOM to do another study.

Now the way in which that RFP or that request for a proposal is drawn, that contract with the Institute of Medicine is something that, frankly, the committee should have direct input in on as well as the veterans service organizations and other advocates because sometimes those contracts are designed to make sure that you don't get at what is the part of the original intent.

And so that would be one way of doing it.

Second I think it would be useful to have the U.S. Government Accountability Office (GAO) in the short term look at some of the areas that we know are of concern. As an example, Alzheimer's drugs, has it had a tremendous negative impact on people not having the latest Alzheimer's drugs? As many of you know, some of our older veterans, even some of the older Vietnam veterans, but certainly the Korean and World War II vets are subject to Alzheimer's. Nobody has come up with a cure for Alzheimer's yet, and we are not suggesting that there is. All you can do is slow it down. So when you slow down those new medications that are coming on the market and have come on the market in the last 3, 4, 5 years from being available to those World War II and Korean veterans, they are never going to get better after they have—by the time VA puts it on the formulary, if indeed they ever do under existing circumstances.

So what I am saying is that you can look at that and point to problem areas with the help of GAO at the same time that you pursue a study with the Institute of Medicine, ma'am.

Mrs. HALVORSON. Great. Thank you. I appreciate your suggestion.

Mr. Bullman, I know that the VA is not a member of your group. What kind of suggestions could you give us? Because it sounds to me like it is a wonderful group to be able to help our veterans maybe take their medications the right way, because, first of all, we are talking about the fact that we are having trouble getting them. But once we get them, we are finding out that one of the major problems is following up and making sure that they not only take it, but they take it in the right doses and finish the medication.

Do you have any suggestions for all of us in order to help the veterans in our system?

Mr. BULLMAN. That is a great question, and NCPIE would certainly invite and encourage the VA to become a member of our Council, but that said, we work oftentimes with representatives from VA pharmacy on the various external coalitions, such as the National Coordinating Council for Medication Error Reporting and Prevention, for example.

The materials that NCPIE makes available, not just our brochures and pamphlets and things like that, but reference-based reports I think would certainly be conducive for helping to at least raise the issue and the impact of nonadherence.

The best medicine in the world taken inappropriately or incorrectly will have no impact and leads to the downstream problems and sequelae that we are talking about here. Our mantra has been for 25 years, "Educate Before You Medicate." And we provide the educational tools and resources for both the healthcare team, physician, pharmacist, nurse practitioner, physician assistant, the questions to ask. But there needs to be that commitment of a teachable moment at the point of not just prescribing, dispensing but throughout the patient pathway, when he or she has the opportunity to either ask questions, recognizing the reluctance of consumers and patients who are vulnerable and critically ill often to ask questions. There needs to be the involved role of the caregiver as well. So there are no magic bullets here, but there is a lot of practical hands-on time and involvement.

The art of medicine needs to come back into this. And part of the art of medicine is communication. So everything that we do is about moving patient and healthcare providers to an equally positioned discussion about medicines and safe medicine use.

Mrs. HALVORSON. Thank you.

And thank you, Mr. Chairman.

Mr. MICHAUD. Thank you very much.

Mr. Snyder.

Mr. SNYDER. I just have one question, Dr. Hoadley.

Did you have any response to, there were some comments made I think that referred to your previous testimony that I didn't hear? Do you have any comments you want to make about the last few minutes of discussion of question and answer?

Dr. HOADLEY. I think some of the suggestions that Mr. Bullman was just talking about are great suggestions in terms of trying to improve adherence, making sure people are well-informed about the medications they are taking.

On some of the other comments about the formulary and its treatment of newer drugs, I think a couple of things should be kept in mind. We really had a number of studies recently that suggest, for at least some drug classes, some of the older tried-and-true medications turn out to be just as effective or even more effective than some of the newer medications. So it is important to realize that newer does not necessarily equal better drugs.

Beyond that, I think the question of the ability to get exceptions from the formulary is really a critical one, and our numbers suggest we are seeing three-quarters of a million prescriptions for a nonformulary drug like Lipitor for cholesterol. There are various numbers that can be looked at, but in the end, the real question could be served by some kind of additional study. A survey of physicians is one way to do that, to simply find out whether the physicians that are treating the veterans do feel themselves that they are able to prescribe the drugs that they really want to prescribe and whether they feel it is as difficult to get exceptions as Mr. Weidman suggested in his comments or whether the numbers that I see in terms of the actual number of prescriptions for some of these nonformulary drugs suggest that they are able to get prescription exceptions when needed. I think that that is something that empirical evidence can be brought to, and we can understand that question better.

Mr. SNYDER. Mr. Weidman, what is your sense from veterans that are in the system—I think you talked about this, too, but if you would amplify on that. You and I are both Vietnam veterans. If I were to go down to the VA clinic, I was there a day or two ago, I mean at the hospital a day or two ago, what is your sense of how quickly it would take to get a nonformulary drug approved? I mean, if I am sitting there with a primary care doctor, is it just a matter of him writing a special prescription that says "this drug only" or——

Mr. WEIDMAN. No, it is not.

Mr. SNYDER. What is the length of the approval process and the length of time? Is it cumbersome?

Mr. WEIDMAN. It depends on the type of drug, and it depends on how expensive it is, at least that is what I gather from the outside and talking to clinicians and talking to veterans who have been told this by their clinician, and some, in some cases, it can take up to a week or 2 weeks about whether or not to go with the off-formulary. Some things like the atypicals, like schizophrenia, they say you have to go for 3 months on the generics, and then, if it doesn't work, then we will try to use the atypicals.

Well, you know, it is like what I was talking about before with the misuse of comparative effectiveness. If you are part of the 15 percent that the generic does not work as well for, and your physician has some reason to believe that that is the case, you are in duck soup, because you can't get this stuff that you need.

And we have had that experience with diabetes medication that people were seeing somebody on the outside, and then they go to

the VA because they, typically what happens is the Vietnam vet who is in-country, finds out that it is service-connected presumptive or he or she retires or loses their job, and then they turn to the VA for their healthcare, and then they discover that the diabetes medication they have been on for 5 years or 3 years, you can't get at VA, and it is very hard to get those exceptions.

It took us, I think it was 8 months, 9 months, pressing hard to get the long-lasting insulins added last year to the VA formulary, and we had to go with the white paper. And it was through the good offices of this Committee that it finally got added on to the formulary, because people couldn't get it, virtually, by going off-formulary through the process.

Mr. SNYDER. Thank you.

Thank you, Mr. Chairman.

Mr. MICHAUD. Thank you.

Once again, I would like to thank each of you for your testimony today. There might be some additional questions that we will ask in writing. Hopefully you will respond in a timely manner. I really appreciate each of your testimonies here this afternoon, so thank you.

I would like to ask the second panel to come forward. While they are coming forward, we have Solomon Iyasu, who is a Director of a Division within the FDA, U.S. Department of Health and Human Services (HHS). We also have Belinda Finn who is accompanied by Irene Barnett, who are both from the VA Office of Inspector General.

I want to thank all three of you for coming here this afternoon to give your testimony, and we will start off with the good doctor.

STATEMENTS OF SOLOMON IYASU, M.D., MPH, DIRECTOR, DIVISION OF EPIDEMIOLOGY, OFFICE OF SURVEILLANCE AND EPIDEMIOLOGY, CENTER FOR DRUG EVALUATION AND RESEARCH, FOOD AND DRUG ADMINISTRATION, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; BELINDA J. FINN, ASSISTANT INSPECTOR GENERAL FOR AUDITS AND EVALUATIONS, OFFICE OF INSPECTOR GENERAL, U.S. DEPARTMENT OF VETERANS AFFAIRS; ACCOMPANIED BY IRENE BARNETT, PH.D., AUDIT MANAGER, BEDFORD OFFICE FOR AUDITS AND EVALUATIONS, OFFICE OF INSPECTOR GENERAL, U.S. DEPARTMENT OF VETERANS AFFAIRS

STATEMENT OF SOLOMON IYASU, M.D., MPH

Dr. IYASU. Thank you, Mr. Chairman.

Mr. Chairman, and Members of the Subcommittee, I am Dr. Solomon Iyasu, Director of the Division of Epidemiology within the Office of Surveillance and Epidemiology for Center for Drug Evaluation and Research of the Food and Drug Administration.

I am pleased to be here today to discuss FDA's role in identifying and communicating drug safety issues as well as our collaboration with Veterans Affairs. FDA is charged by Congress with the authority to review new drug applications for safety and effectiveness. Adverse reactions reported during the clinical trials of the drug are included in the labeling information.

All drug products contain risks as well as benefits, and it is often impossible to predict which individuals may have increased sensitivity to particular drugs. No amount of premarket study can provide all of the information about the effectiveness or all the risks of a new drug when it is used by the general population.

Once FDA approves a drug, the post-market monitoring stage begins. A drug manufacturer is required to submit regular post-market reports to FDA. Also, FDA receives adverse-event reports directly from the public through our MedWatch Program. These reports are reviewed and analyzed by FDA epidemiologists and safety evaluators to assess the frequency and seriousness of the adverse events and to determine their association with medication usage.

As more becomes known about the potential risks or benefits of a drug, often its FDA-approved labeling will be revised so that it better reflects information on appropriate use. If labeling alone is inadequate to manage risks, additional actions may include revising drug name or packaging, issuing "dear healthcare professionals" letters, disseminating educational special-risk communications, or requiring restrictive distribution programs.

FDA uses a broad range of methods to communicate drug safety information to the public. The different types of drug safety communication includes labeling, early communications about ongoing safety reviews, public health advisories, healthcare professional sheets, and other methods of communication, such as video broadcasts and conference calls.

Manufacturers also use various methods to communicate drug safety information. A manufacturer may distribute a "dear healthcare professional" letter to convey important information regarding the marketed drug.

FDA's Drug Safety Oversight Board was established in 2005 to oversee the management of drug safety issues and communication to the public about the risks and benefits of medicines. The board is made up of FDA and medical experts from other government health agencies and government departments, including Veterans Affairs.

Along with other FDA colleagues, I am a primary participant from the Office of Surveillance and Epidemiology (OSE) in addition to the OSE Director and my counterpart in OSE's Division of Pharmacovigilance.

Also, the FDA and Veterans Affairs have a memorandum of understanding (MOU) for sharing information to enhance post-market surveillance efforts and other drug and vaccine safety projects. The goals of the collaboration are to explore ways to promote efficient use of tools and expertise for product risk identification, validation, and analysis, and to build infrastructure and processes that meet shared needs for evaluating the safety, efficacy and use of drugs, biologics and medical devices.

In August 2008, the FDA and Veterans Affairs signed an interagency agreement which allowed FDA to provide funding to Veterans Affairs for work on safety issues of mutual interest. This agreement allowed funding for personnel time and programming costs associated with analysis of VA data to explore questions of interest that were raised by FDA but also of interest to Veterans Af-

fairs. It is currently in the process of being renewed for another year.

In September 2007, Congress passed the Food and Drug Administration Amendments Act, which included new resources for medical product safety that requires the HHS Secretary to establish a post-market risk identification and analysis system to link and analyze healthcare data from multiple sources. The Sentinel Initiative is FDA's response to this mandate. Its goal is to build and implement a new active surveillance system that will eventually use electronic health information to monitor the safety of all FDA-regulated products.

The Sentinel Initiative is a long-term effort that must proceed in stages, and this effort is well under way. The FDA is collaborating with the Federal and private sectors in various activities that would inform the development of this system.

In December 2008, the FDA held a public meeting on the Sentinel Initiative to obtain input from stakeholders about the structure, function, and scope of the project. The Director for the Center for Medication Safety of the Department of Veterans Affairs was among the participants at this day-long meeting, presenting on the issue of risk communication.

After the initial step of creating the Sentinel System, the FDA is initiating various pilot efforts to further the science of medical product surveillance. One of these pilots, known as Mini-Sentinel II, would include our Federal partners. We look forward to the VA's participation in this effort. The effort involves creating a distributed system that will focus on developing methodologies to obtain more information on emerging drug safety issues. The Sentinel System will augment the Agency's current post-market surveillance tools to strengthen FDA's ability to ensure that safe and effective new drugs are available to the public, and that the risks of marketed drugs are well understood.

The FDA has a critical role in the detection and management of safety issues that are identified after a drug is approved, including a critical role in communicating information to the public. Our goal is to make the most up-to-date drug safety information available to the public in a timely manner so that healthcare professionals and patients can consider the information when making decisions about medical treatment. Our ability to fulfill our mission is enhanced by our partnerships with patients, physicians, pharmacists, industry, State regulators and other partners like Veterans Affairs. Together we can help ensure the safe use of marketed drugs by providing the best possible information to the American public.

Once again, thank you for the opportunity to testify to the Subcommittee today.

[The prepared statement of Dr. Iyasu appears on p. 53.]

STATEMENT OF BELINDA J. FINN

Ms. FINN. Chairman Michaud and Members of the Subcommittee, thank you for the opportunity to be here today and discuss VHA's accountability for noncontrolled drugs. We have recently issued two audit reports that address systemic weaknesses at VHA's medical facilities and consolidated mail outpatient pharmacies, commonly known as the CMOPs.

Joining me today is Irene Barnett, an audit manager from our Bedford audit office.

In 2008, VHA medical facilities and the 7 CMOPs dispensed about 126 million prescriptions and spent $3.7 billion on pharmaceuticals. About 95 percent of those dollars went for noncontrolled drugs. Although noncontrolled drugs are not subject to the stringent inventory and oversight controls, they are subject to diversion, since they are often expensive, have a high street value, or contain active ingredients that can be used to manufacture illicit drugs.

We reported VHA medical facilities and the CMOPs could not adequately account for their noncontrolled drugs because of inadequate inventory management practices, recordkeeping, and inaccurate pharmacy data.

At the CMOPs, we found pill count differences ranging from a negative of 3,100 pills to a positive 192,000 pills. At the medical centers we also identified both positive and negative variances. For example, 24 of 31 medical facilities reviewed had a positive variance for at least 1 drug. These positive differences in pill counts are significant because they represent pills that are available to dispense or divert without anyone knowing since they don't exist according to the records.

Physical inventories act as a check on the effectiveness of other inventory controls; however, the VHA's VistA system cannot maintain a perpetual inventory that would provide accurate information.

We also found problems with the recording of drug transactions. For example, the local pharmacy personnel were not consistently recording returns to stock from the pharmacy. Physical security controls were in place at the CMOPs we visited to prevent the unauthorized physical removal of pharmaceuticals; however, the inventory systems contained 61 users who could order, receive, and adjust inventories without any oversight.

Those same CMOP inventory systems contain generic user accounts that allowed employees to anonymously order drugs, reduce the inventory balance, and divert the drugs.

Finally, when the physical and the inventory counts don't match, CMOP personnel simply adjust the inventory balance to match the physical count.

In 2003, VHA initiated the Pharmacy Reengineering Project to improve VistA's accountability for drugs. Although this system development was originally slated for completion in 2005, it has experienced significant delays and is currently halted for a review.

During our reviews, we recommended the Under Secretary for Health improve accountability over noncontrolled drugs by enforcing annual wall-to-wall inventories, establishing better control over drug transactions, and correcting the CMOP information security weaknesses.

The Under Secretary for Health agreed with all of our recommendations and has provided acceptable plans to implement our recommendations and correct the weaknesses.

That concludes my statement. We will be happy to answer any questions you may have.

Mr. MICHAUD. Thank you very much. It has been very helpful.

[The prepared statement of Ms. Finn appears on p. 58.]

Mr. MICHAUD. Do you believe that the national CMOP remains the preferred model for acquiring pharmaceutical supplies and services, and are you aware of whether that is the same process that the DoD goes through?

Ms. FINN. I can't speak to the DoD process. I know the CMOP model and the VHA model of a prime vendor to centrally acquire and distribute pharmaceuticals and supplies has been an effective model for VHA. It is actually managed and operated out of the National Acquisition Center, the contracts that supply the pharmaceuticals and the supplies. And I believe VHA gets effective pricing, probably about 26 percent better on pharmaceuticals than other Federal customers.

Mr. MICHAUD. You mentioned the monitoring of inventorying for noncontrolled drugs. Do you have a sense of whether this is an issue in the private sector, and if not, do you think the VA can learn something from the private sector as it relates to monitoring their inventorying? Or do you think the recommendation that you made to the VA would be sufficient to take care of the problem that is out there?

Ms. FINN. During our review we did speak to pharmaceutical managers in the private sector, and they did provide monitoring over noncontrolled drugs that they considered subject to diversion.

Also, during our review we found a number of VHA pharmacy managers were monitoring drugs even before our work. And after we conducted our work and noted the differences between the physical inventories and the actual drugs on the shelf, many of those managers took steps to monitor more drugs.

So I think at this point I would consider our recommendations a good step forward. In a few years perhaps we will go back and determine whether or not more action is needed.

Mr. MICHAUD. Doctor, in your testimony you noted that the FDA and VA signed an interagency agreement allowing FDA to provide funds to the VA to work on safety issues of mutual interest. Can you expand more on this point, and do you have the same type of agreement with DoD?

Dr. IYASU. The kind of work that we do under this interagency agreement is—it comes under the greater umbrella which is the MOU, the memorandum of understanding that we have between the FDA, VA, and DoD. We specifically have this interagency agreement with VA to work on emerging safety issues, and some of the examples I have included in my written testimony where rapid analysis can be done of safety information that is available within the VA system either from the adverse event reporting system or from their MedSafe database.

So this is a unique collaboration in terms of having access to electronic medical record data that VA is uniquely equipped to sort of amplify on safety issues that we may have a concern about, and it is also affecting the VA population.

So specific studies are agreed upon where the study protocols that develop the hypotheses is developed, but the work is actually done within the VA system while the part about sharing of the information comes under the MOU, and the FDA may get information on the aggregate results. And there are specific examples like working on propoxyphene-containing products where the VA data-

bases have been very helpful in informing the regulatory decisions pertaining to the actions the FDA took.

Mr. MICHAUD. How does the FDA approve drugs? It is my understanding you have a committee that looks at drugs and makes a recommendation whether or not a drug should be approved by FDA. Or how does that process work?

Dr. IYASU. The approval process for new drugs is we have the NDA process for new drug applications. So the companies have to provide all of the information that has been collected over the development period, and this starts from the preclinical period and through the three stages of the clinical studies.

And so all of the data are reviewed by FDA personnel, medical officers in all disciplines. And most of the decisions are based on whether there is adequate information to say that the drug is safe and effective for its intended use. And this is done by the collaboration of multiple disciplines, but the lead responsibility is by the Office of New Drugs, and mostly within the Center for Drug Evaluation and Research.

So when data are very controversial in terms of the effectiveness data or the safety data that may be stemming from the clinical trials, we may seek, also, advice from outside experts. So we seek advice through the advisory committees that we have set up for different therapeutic areas.

Mr. MICHAUD. My last question is, we do not deal with the FDA in this Committee, but I have heard complaints about FDA's progress for approving drugs and other issues that deal with conflicts of interest. I think a couple of years ago a drug—I think it was Prozac—was placed on the FDA approval list by the Committee. They have a lot of veterans who are very supportive of and encourage that; however, there is a concern about conflict of interest with a certain doctor within FDA.

Recently I read an article dealing with the same issue with amalgams in mercury and the potential conflict of interest there as well. And when you look at prescription drugs, there is big money involved.

How does FDA deal with complaints about conflict of interest within the FDA, or do you just brush them off?

Dr. IYASU. That is actually a good question. I am not an expert in that area of conflict of interest, but I would be very happy to take back the question and provide more detailed answers to your concern.

Mr. MICHAUD. Thank you.

[The FDA subsequently provided the information in a follow-up letter, dated November 6, 2009, which appears on p. 68.]

Mr. MICHAUD. Mr. Snyder.

Mr. SNYDER. Thank you, Mr. Chairman.

I need you to educate me here. Ms. Finn, is this an inventory problem, or is it a recordkeeping problem of the—at the time drugs are prescribed? Where is the accuracy and the inaccuracy? When you go in and count up the number of drugs and pills in the storeroom, do we think that is accurate and that the recordkeeping was wrong, or do we think the recordkeeping is right, but somehow either too many pills were sent in, or some were walking out the door in-house? Which is the problem, or do you know?

Ms. FINN. The problem is we can't tell which is actually accurate because the physical inventories are different from the records. We know there are problems with the transactional records, and we know there are problems with the actual taking and recording of the physical inventories.

Mr. SNYDER. Okay. The problem is on both ends.

Now, if somebody had asked me, you know, an hour ago when I got to the airport do I think that somebody could make a phone call to a VA hospital pharmacy and say, you know, how many Lipitor 40 milligrams were prescribed last year, I would say, yeah, they can probably do that in an hour. But apparently that is not right. I thought because of the electronic recordkeeping, there would be an ability to come up with those numbers fairly quickly. Is that right or wrong?

Ms. FINN. They may be able to give you an answer. I can't vouch for its accuracy.

Mr. SNYDER. So let us suppose it was inaccurate. Where would the inaccuracy come from? Prescriptions are written, and they never get sent to a patient?

Ms. FINN. Part of the problem that we saw is the pharmacy may dispense pills using a reprint function which may not actually hit the pharmacy records, so there could be prescriptions dispensed that aren't being recorded because they are using an informal method.

Mr. SNYDER. Now, in terms of the inventory, you had quite a range of potential problems, right? Do we think at any time that this interferes with veterans getting medications? Because of the inaccuracies or inefficiencies, are sometimes veterans getting prescriptions, they are told by the pharmacist, well, this one isn't in, we didn't order it in a timely fashion, or not?

Ms. FINN. No, sir. We didn't see any evidence of any harm to veterans because the pills were not available.

Mr. SNYDER. I don't mean harm. I just mean inconvenienced.

Ms. FINN. No. None of that either.

Mr. SNYDER. So then it becomes an issue of cost.

Ms. FINN. It becomes an issue of cost and accountability.

Mr. SNYDER. Thank you, Mr. Chairman.

Mr. MICHAUD. Once again, I would like to thank the panelists. They have been very helpful. I look forward to working with you as we move forward trying to address some of the concerns that we have heard from the veterans community. So once again, I thank each of you for coming today.

Our last panel is Mr. Valentino, who is the Chief Consultant over at the Department of Veterans Affairs. He is accompanied by Dr. Good and Dr. Tibbits.

I want to thank all three of you for coming forward this afternoon. I look forward to your testimony.

Mr. Valentino, without any further ado, I would open it up to you.

STATEMENT MICHAEL A. VALENTINO, R.PH., MHSA, CHIEF CONSULTANT, PHARMACY BENEFITS MANAGEMENT SERVICES, VETERANS HEALTH ADMINISTRATION, U.S. DEPARTMENT OF VETERANS AFFAIRS; ACCOMPANIED BY CHESTER B. GOOD, M.D., MPH, CHAIR, VETERANS AFFAIRS MEDICAL ADVISORY PANEL, VETERANS HEALTH ADMINISTRATION U.S. DEPARTMENT OF VETERANS AFFAIRS; AND PAUL TIBBITS, M.D., DEPUTY CHIEF INFORMATION OFFICER FOR ENTERPRISE DEVELOPMENT, OFFICE OF INFORMATION AND TECHNOLOGY, U.S. DEPARTMENT OF VETERANS AFFAIRS

Mr. VALENTINO. Mr. Chairman, Ranking Member and Members of the Subcommittee, thank you for providing me this opportunity to discuss VA's Pharmacy Benefits Management Services program, including our national Formulary and patient safety initiatives.

I am accompanied today by Dr. Chester B. Good, Chair of the Medical Advisory Panel, and Dr. Paul Tibbits, Deputy Chief Information Officer for Enterprise Development.

Each veteran enrolled in the VA healthcare system is eligible to receive prescription medications, over-the-counter medications, and medical and surgical supplies under VA's comprehensive medical benefits package.

In 2008, VA provided approximately 126 million outpatient prescriptions to more than 4.4 million veterans. I can say with confidence that VA is meeting the pharmaceutical needs of veterans, and that we are striving every day to provide even better care to more of America's heroes.

I have some very good news to share. Just last Thursday, J.D. Powers and Associates, the widely recognized customer satisfaction and quality analysis firm, released the results of its third annual pharmacy customer satisfaction survey. This survey evaluated both community and mail-order pharmacies, including VA's consolidated mail outpatient pharmacies, or CMOPs. VA CMOP program ranked third overall for the mail-order pharmacy category, scoring 875 out of a possible 1,000 points. Only Kaiser Permanente at 877 points and Prescription Solutions at 876 points performed better than VA. All three organizations received the same overall ranking of "among the best," the highest-ranking designation J.D. Powers and Associates offers. This is exceptional news, and we thank this Committee and Congress for making this success possible.

VA's pharmacy benefits program works to enhance the clinical outcomes and improve the health of veterans through the appropriate use of pharmaceuticals. This program consists of six primary specialty areas: the Clinical Informatics section; CMOPs; adverse drug event reporting; Emergency Pharmacy Services; VA National Formulary management; and the VA Center for Medication Safety, or VA MedSafe. I will briefly explain how each of these programs provides better care to veterans.

First, the Pharmacy Benefits Management (PBM) Clinical Informatics section provides operational oversight to the information systems used by PBM and all VA pharmacies. This section is responsible for developing the functional requirements for the Pharmacy Reengineering Project, which, when completed, will provide a system to enhance patient safety and encourage the appro-

priate use of pharmaceuticals by providing integrated, streamlined decision-making to clinical staff.

Second, VA operates seven CMOPs that provide prescription fulfillment services to VA healthcare facilities. CMOPs support VA's healthcare mission through advanced automated production technologies to dispense and mail prescriptions to eligible veterans. This ensures each veteran receives his or her prescriptions in the most timely, accurate, and cost-effective manner as possible. Three out of five CMOP performance metrics currently exceed six sigma performance.

Third, by collecting and evaluating adverse drug events through VA's Adverse Drug Event Reporting System, VA is able to identify drug safety signals, assess significance of external drug safety issues in our own patients, and track trends of known drug safety issues almost instantaneously. This process is facilitated by VA's electronic medical record, which links prescription data to clinical outcomes at the patient level.

Fourth, the Emergency Pharmacy Services section is responsible for procuring, storing, and maintaining emergency pharmaceutical and medical or surgical supply items for the Department. This section works closely with other groups within VA to ensure we are ready to respond to an emergency with supplies at VA Medical Center storage sites nationwide. VA can also deploy mobile pharmacies to provide targeted local support.

Fifth, VA's National Formulary was consolidated into a single formulary in 2009. VA experts monitor the medical literature, scientific research and VA outcomes data to identify evidence that may support adding drugs to or deleting drugs from the formulary, and by drafting evidence-based prescribing guidance. VA develops guidance on the pharmacologic management of common and high-cost diseases and collaborates with clinical experts within the Department to develop or refine guidance when necessary.

Finally, VA MedSafe is a national comprehensive pharmacovigilance program that emphasizes the safe and appropriate use of medications. VA strives to ensure that veterans receive the right medications in the right dose at the right time. VA is frequently cited as a leader in the field of pharmacovigilance by some of the leading experts in the field, and currently has a formal collaboration agreement with the Food and Drug Administration and the Department of Defense in this important area.

Mr. Chairman, VA has developed a remarkable pharmacy benefits management system that provides veterans safe and effective medication to improve their healthcare. Our National Formulary is based on the best clinical research and leverages the size of our patient population and the Department to procure medications at a low cost.

Thank you again for this opportunity to testify, and my colleagues and I are prepared to answer your questions.

Mr. MICHAUD. Thank you very much, Mr. Valentino. I appreciate your coming here today.

[The prepared statement of Mr. Valentino appears on p. 61.]

Mr. MICHAUD. You sat through the first panel and the second panel, and you heard some of the concerns raised by both panels. And one of the concerns is the fact that formulary decisions are not

conducted in a transparent process, they are made behind closed doors. With the administration's commitment to transparency, what are your comments on how you can make the process more transparent? Are you familiar with the DoD process? What is wrong with having the same system as the DoD that is transparent compared to the VA system?

Mr. VALENTINO. I am familiar with the DoD process.

We do have a fair amount of transparency in our process. We develop our evidence-based documents, literature reviews, drug class reviews. We vet them internally. Everyone has a bite at the apple in VA, frontline clinicians, physician managers. We send them out far and wide for comment before we finalize those documents which ultimately are posted on our Web site and then are accessible by the public for further comment and feedback.

We use VA physicians and VA pharmacists to manage the formulary process. Cost is really not considered until the very end of the process. We spend a lot of time focusing on safety primarily and efficacy of the products that we review. Cost is certainly a consideration, but it is only considered at the very end and certainly does not trump safety and efficacy.

In regards to getting input, there are a lot of meetings that are held at the local and regional level with veteran service organizations regarding the formulary. I think there is a lot of collaboration and a lot of communication that takes place at that level which does filter up to our level.

So we are always ready to receive comments, to work with folks about the formulary issues. We don't seem to get that many comments about the decisions that we have made. As Dr. Hoadley testified, our physicians seem to be fairly happy with the process and their access to nonformulary drugs. If we believe that J.D. Powers survey, our patients appear to be pretty happy as well. VA pharmacy usually scores pretty high in our internal customer surveys, so we believe we do have a fairly open process.

Mr. MICHAUD. Do you think the reason why you don't get very many comments, from what I heard from earlier panels, is because it is a secretive process? I don't know the DoD formulary process, but would you be opposed to having VA go through that same process, because that appears to be more transparent than what VA is going through. If not, what are your objections to the DoD process?

Mr. VALENTINO. I have not studied the DoD process in detail. I know they have a Beneficiary Advisory Panel that is advised of the decisions after the executive committee makes their decisions.

I would be very happy to consider such a proposal for VA.

Mr. MICHAUD. When you look at what our soldiers are currently going through today in Iraq and Afghanistan, TBI. We heard from Mr. Weidman earlier that seizure medications are not part of the formulary. I find that astonishing since this is a signature wound of the war in Iraq and Afghanistan. Is that correct, and if so, why wouldn't that be on the formulary since we are hearing so much about TBI and post-traumatic stress disorder?

Mr. VALENTINO. We do have a large number of seizure medications on the formulary. We review all new drugs as they are approved by the FDA. Frequently it takes a little bit of time before we get published information in the literature so we can make a

better assessment of the safety and efficacy. But we do—I believe that we do have a very good selection of drugs for seizures on our formulary currently; and importantly, if we don't have one that somebody needs, it is available through the nonformulary process. Our policy requires that we adjudicate those nonformulary requests within 96 hours. And we have our various sites report that information to us quarterly. So we do have a fairly rapid way of doing that.

Our policy also says if you need the drug urgently, the time period to get it is immediately. We don't rely on the 96 hours. So typically that would occur in the inpatient setting. But for out-patient drugs where someone needs to switch from one drug to another, that typically happens rather quickly.

I would ask my colleague to comment further on the antiseizure medications.

Dr. GOOD. I think also was mentioned atypical antipsychotics, that they weren't on the formulary, and I believe most of the atypical antipsychotics are on the formulary and are used in these patients with TBI. And we have a wide variety of antiseizure medications.

Mr. MICHAUD. I believe in Mr. Weidman's testimony, though, he mentioned how difficult it is to get drugs off the formulary. That is a big concern that I have, plus the fact that there are a lot more drugs on the DoD formulary. For instance, you may have a soldier at Walter Reed who is on medication, on drugs that are not on the VA formulary, then they get transferred over to the VA system. Have you run into problems in that particular area as well?

Mr. VALENTINO. Early on we heard of some issues with veterans who are on convalescent leave. They are still on Active Duty, and they were receiving care at a VA close to their residence. They were coming to us on very sophisticated pain medications that were given by a pump with special tubing, special concentrations of medications. It did take us just a small bit of time to become accustomed to that equipment, get the necessary supplies in.

At that time we did communicate with the field, and we advised them that patients who fit into this category, they are on convalescent leave; they are just getting their care at the VA; they need to get whatever they are on regardless of whether it is on the formulary or not on the formulary, no questions asked. And I have not heard of any problems in that area since that time.

Mr. MICHAUD. Mr. Perriello?

Mr. PERIELLO. Thank you, Mr. Chairman.

Congratulations on the J.D. Powers and Associates ranking, and I think there are some signs of progress and success that are encouraging, but also obviously some concerns. One of particular interest to my heavily rural district is access to care. I wanted to hear a little more about the policy rationale for the VA not filling prescriptions by non-VA doctors and what some of the rules are for that. This is especially burdensome for rural veterans who have to travel a long way to get these prescriptions signed.

Mr. VALENTINO. Thank you.

There are a small number of prescriptions that we can fill for—written by non-VA doctors, the CHAMPVA program is one example, Aid and Attendance is another example, fee basis is another

example. But by and large, it has to do with the makeup of our process.

As Dr. Hoadley testified, we offer a prescription benefit as part of an integrated comprehensive medical care model. Our prescription benefit is not an add-on, it is not a stand-alone program, and that is a clear difference between some other programs where you can just send in your prescriptions. We believe that to do so, to provide prescriptions in that manner, would possibly compromise the quality of care, because we don't have the complete picture in regards to what that patient might be getting from various sources; not just from our pharmacies, but from other pharmacies.

We do have programs with some of our contracted CBOCs in the rural areas so that patients can get their prescriptions filled at a community pharmacy under contract at VA expense, and then refills are sent to them via mail through our Consolidated Mail Outpatient Pharmacy program.

Mr. PERIELLO. Is there room to expand on any of those or otherwise improve? I mean, while protecting the quality of care arguments and wanting the comprehensive sense of a medical home and all of the factors for a VA patient, isn't there something between where we are now and those concerns where we could see greater expansion of non-VA filling of prescriptions and the like?

Mr. VALENTINO. I am sure anything is possible. We did have a program for a few years called the Transitional Pharmacy Benefit Program, and it was designed to ease the out-of-pocket cost for patients who were waiting more than 30 days for their initial primary care appointment. We found that it was extremely difficult to administer our program under that model because of the unfamiliarity of the prescribers with our formulary. We also found that the number of eligible patients who could participate as compared to those who actually did participate was low. In other words, not very many people took advantage of that program.

So to answer your question, yes, I think that there are lots of alternatives that we could consider.

Mr. PERIELLO. Are there particular barriers to doing it that are ones where we would need to be involved, or is this a matter of piloting some of these potential other ideas?

Mr. VALENTINO. Well, one of the big issues has to do with the electronic medical records. That is really a huge safety tool for us. Our prescribers are able to order medications electronically. They are reviewed by a pharmacist. We check to make sure the right dose is there, that the patient isn't on other medications.

So if we were to start to fill a lot of prescriptions from non-VA providers, we would lose that important safety mechanism. That would cause us concern over the safety of the product that we are dispensing. In other words, is it the right drug for that person, is it going to interfere with other drugs that he may be getting?

Mr. MICHAUD. Thank you very much, Mr. Perriello, and also for your leadership on veterans issues. We really appreciate your tenacity in making sure we take care of our veterans. So thank you.

Just a couple more questions, Mr. Valentino.

I don't know if you had a chance to read the Inspector General's report issued in June of 2009, the audit report. What steps has the

VA taken to address the issue that was addressed in that report regarding the noncontrolled drugs and the CMOP contract?

Mr. VALENTINO. We looked at each of the six recommendations. We concurred with the recommendations. We have drafted a policy regarding the inventory controls over noncontrolled medications. We have communicated our expectations verbally on a number of conference calls, a number of e-mail bulletins that we sent out. So we have told people what we want them to do.

We have developed a policy that is currently under review in the concurrence process. That is, our short-term or our interim solution is to just try to do more education, try to develop the policy. We also are working with the network office to have the System-wide Ongoing Assessment and Review Strategy (SOARS) teams that go out and do assessments and take a look at this particular area, make sure all of the policies are being followed.

Our long-term solution has to do with the pharmacy re-engineering effort and some of the requirements that we have developed for inventory management.

So that is really where we think we are going to make the most gains. We have a lot of remote dispensing cabinets within VA. We want to be able to get the inventories in those cabinets rolled up along with the outpatient inventories, the intravenous inventories, the unit dose inventories, into a single place, and that will give us the ability then to match what we purchase with what we dispense.

And as we heard earlier, you really need to monitor everything basically. You need to have a perpetual inventory system if you want to have more confidence in the process.

Mr. MICHAUD. You heard Dr. Lichtenberg's testimony, in which he explained that older drugs on the VA formulary result in shorter lives for our veterans. Any comment on that?

Mr. VALENTINO. Yes, I do have some comments. And if I may, I have a couple of posters that I would like to share that helps illustrate that.

This is a graph from the report that was mentioned, and it shows the veteran's life expectancy versus life expectancy at birth of all U.S. males. And when you look, everybody I have showed this to says, Oh, my word, veterans are not living as long as their counterparts. Well, there are a couple of problems with that.

You will notice there are two Y axes here. So we have corrected this chart to show what it would actually look like if you put everything on the same axis.

I would also point out that the veterans used in this study are all U.S. veterans; not veterans that get care at VA, not veterans that are enrolled in VA, all veterans. So we have some concerns.

This is actually what we believe is the true picture. In fact, veterans—and again, these are not veterans that receive care in VA. This is the same data. They actually live longer than their counterparts. So I wanted to show this to illustrate some of the concerns that we have with the report.

There are a number of issues. We have not had a 1-year moratorium on drugs since 2000. And also, as Dr. Hoadley pointed out, formulary status does not imply access. We have a large number of drugs that we dispense on a nonformulary basis. I ran a list of drugs where we have more than 100,000 30-day equivalent pre-

scriptions. Looked at a 12-month period, we filled almost 9 million nonformulary, 30-day prescriptions. That is out of 237 million 30-day equivalent prescriptions. So roughly 4 percent of our utilization is for nonformulary drugs, and that represents about 9 percent of our total cost. So formulary status does not equal access.

Our nonformulary status is very similar to prior authorization or step therapy that you see on other formularies where these drugs are in the second or third tiers.

There are also drugs listed as examples in the report that were withdrawn from the market for safety reasons prior to the report being written. There are also drugs listed that were listed as nonformulary that were on formulary.

So we do not agree with the conclusions in the paper whatsoever.

Mr. MICHAUD. The VVA actually came up with several recommendations in their testimony. I do not know if you had a chance to review those recommendations. If so, would you care to tell the Committee whether you agree or disagree, and, if you disagree, why? And if you can't do it today——

Mr. VALENTINO. A couple of points.

We certainly appreciate the comments, and we truly are interested in anything that can make our system better.

A couple of points that I would point out is regarding the diabetes care, actually in VA diabetes care is very, very good. There are some articles by Kerr that point out that VA care is cost-effective and high-quality as compared to other systems.

The only other thing that I would point out is that we do have some performance metrics, as was mentioned, that are pharmacy related. So we have got performance metrics on diabetes; we have got performance metrics on cholesterol, on hypertension, and in these, when compared to Medicare, Medicaid, and private programs, VA is often the leader in those areas. So we do believe in performance metrics. We absolutely agree that people will perform when you ask them to do something and they know they are measuring it.

The other point is that in regards to the cholinesterase inhibitors, which is the primary drug class used for dementia, Alzheimer's, we currently have two of the three drugs available on the National Formulary, and as with all drugs, if the third one is needed, is medically necessary, there is a process to go through to obtain that.

One example that I think is really—really illustrates quite nicely how cost can be a factor or cannot be a factor is drug treatments for wet AMD, and this is a condition where the macula in the eye—I should probably let Bernie talk about it. You get a proliferation of blood vessels, and it causes you not to be able to see. There are some anticancer drugs that work very well. One is approved by the FDA for this indication, very expensive; the other is not approved by the FDA for this indication, but seems to work well, seems to be safe. It is pennies compared to thousands.

In VA we have made the decision that we are going to go with the FDA drug which costs—go ahead. You talk about it.

Dr. GOOD. The drug is FDA-approved for treatment of macular degeneration, which is a leading cause of blindness in the elderly.

So we made the decision because evidence—the evidence supported use of Lucentis, and even though we were getting calls to use Avastin instead, because it was quite a bit cheaper, because the evidence supported—in the literature supported—and that is our approach, to live and die by the evidence, what we think will best help the veteran. And in this case we thought that by far the more expensive drug for the same indication was what was in the best interest of the veteran.

So this decision made several years ago, which stands today, was to mandate use of Lucentis rather than the far, far cheaper Avastin.

Mr. MICHAUD. My very last question. Why did the VA allow the directive on drug accountability software to lapse in 2003?

Mr. VALENTINO. We have incorporated a lot of our directives into handbooks that are based on themes, National Formulary handbooks, different kinds of handbooks.

We looked at that particular requirement, and we found that although it may seem like it really adds to the security, in fact all it does is tell you about those drugs that you are looking at, as we heard from the OIG. If folks tend to know where you are looking, they go other places.

So we had fully anticipated that we would have the perpetual inventory process in place by now, And so we didn't feel that that requirement should be continued in policy.

Mr. MICHAUD. Thank you.

Any additional questions?

Once again, Mr. Valentino, I want to thank you and Dr. Tibbits and Dr. Good for coming today, as well as the previous two panels with us. It has been very helpful, and we really appreciate it and look forward to working with you to try to address some of the concerns that I heard.

We will adjourn the Subcommittee hearing.

[Whereupon, at 3:45 p.m., the Subcommittee was adjourned.]

A P P E N D I X

Prepared Statement of Hon. Michael H. Michaud, Chairman, Subcommittee on Health

The Subcommittee on Health will now come to order. I would like to thank everyone for attending this hearing.

The goal of today's hearing is to determine whether the VA is meeting the pharmaceutical needs of our veterans. We are conducting this hearing because of the concerns that I have heard from our veterans about proper access to non-formulary prescription drugs, concerns about adverse drug interactions and patient safety, and recent reports by the Office of Inspector General citing the need to better manage certain aspects of the VA's pharmacy benefits program.

When properly designed and implemented, formularies can promote drug therapy that is rational, clinically appropriate, safe, and cost-effective. However, patient care may be compromised if a formulary system is not developed and administered so that individuals can access the drugs that they need. I have heard from veterans who have voiced their frustration with the VA national formulary as being too restrictive to the point that accessing appropriate drugs is a barrier. Some veterans have pointed to a flawed, subjective system for securing non-formulary drugs. For example, a veteran who is denied access to a non-formulary drug at one VA medical center may be approved in another medical center, which suggests that the decision may not be based entirely on clinical factors.

I also have concerns about patient safety and whether we are doing enough to prevent adverse drug events. Among the medication errors leading to adverse drug events are missed doses, duplicate therapy, drug to drug interaction, inadequate monitoring, and preparation error. For example, what is the VA doing to prevent adverse drug events and are they coordinating well with the FDA? What steps is the VA taking to ensure that veterans do not accidentally take their prescribed medicine in wrong doses or do not forget to take their medicine at the right times? Also, how does the VA make sure that they catch potentially adverse drug interactions when veterans get their prescriptions filled both at the VA and at private pharmacies?

Finally, the recently released audit reports from the Office of Inspector General raise concerns about the VA's management of non-controlled drugs and the Consolidated Mail Outpatient Pharmacy (CMOP) contract. Efficient management of the CMOP contract is critical because almost 80 percent of all VA pharmaceuticals are dispensed using the CMOP.

We have our panels of expert witnesses to help us explore these issues today. I look forward to hearing their testimonies.

Prepared Statement of Jack Hoadley, Ph.D., Research Professor, Health Policy Institute, Georgetown University, Washington, DC

Good morning Mr. Chairman and Members of the Subcommittee. My name is Jack Hoadley, and I am a Research Professor at Georgetown University's Health Policy Institute. As a long-time analyst of issues surrounding prescription drug coverage, I have conducted a variety of research projects with regard to formularies and other approaches to managing the use of prescription drugs in Medicare, Medicaid, the VA, and private-sector health plans. I appreciate the opportunity to speak to the Subcommittee on these important issues.

During congressional debates over the Medicare Part D prescription drug benefit, the role of the VA National Formulary has been commonly invoked. Some have pointed to the role of the VA Formulary in helping to achieve low prices for the VA, whereas others have made the claim that access to drugs is more restricted in the VA system compared to private plans, especially the private plans offering drug coverage through Medicare Part D.

A report prepared in December 2006 for the Pharmaceutical Research and Manufacturers of America (PhRMA) concluded that "the application of a VA-style formulary process to the Medicare prescription drug program would significantly reduce physician and patient choice of drugs," and that "a reduction in choice of prescription drugs could be of special concern for the Medicare population."[1] In an April 2007 memo, Greg D'Angelo of the Heritage Foundation wrote that "if Congress fixes prices in Medicare and establishes a restrictive national formulary, the program would be less responsive to the diverse and ever-changing needs of beneficiaries."[2] As a result of those statements, my colleagues and I decided to shed further light on these issues by conducting an objective comparison of the VA National Formulary to formularies used by Part D plans.

We examined a sample of 160 commonly prescribed drugs and compared their status on the VA National Formulary to comparable unrestricted coverage for a variety of Medicare Part D plans. In general, we found that the VA listed fewer drugs on formulary, but our analysis of off-formulary prescribing at the VA suggests that this does not translate into less access to the drugs than exists under Medicare Part D.

Background

Formularies were used by veterans' medical centers as early as 1955 to help manage pharmacy inventories. In 1995, the VA took steps to consolidate its bargaining power with drug makers and thus reduce spending. It combined the formularies of local VA medical centers to create a single formulary in each of 21 Veterans Integrated Service Networks (VISNs). Two years later, it implemented a national formulary, and by 2007 the VA had completed the process of phasing out the VISN drug lists, making the national formulary the definitive and only VA drug list.[3]

The VA National Formulary functions somewhat differently than most formularies maintained by private organizations. Since the VA is an integrated system – meaning that veterans go to VA facilities to see VA doctors and fill prescriptions at a VA formulary – the VA has a great deal of leverage to promote the use of a single formulary within its facilities and patient pool. This distinguishes the VA formulary from those used by most private insurers. In most private plans, a drug's formulary status might not be known by a physician when a prescription is written, but instead only determined at the point of sale by the pharmacist, when the patient brings a prescription to be filled at the local pharmacy. In those cases, the prescribing physician has no particular relationship with the insurer or health plan. The VA system is more like group and staff model HMOs such as Kaiser Permanente, where the formulary is viewed as a clinical tool to be used by physicians, rather than an enforcement tool of the plan applied at the pharmacy.

The VA National Formulary is managed by practicing VA physicians and regional formulary managers and takes into account safety, efficacy, and cost in deciding what drugs to list on the formulary. As part of the process, VA clinicians have an opportunity to provide input on the decisions, which helps to create a sense of buy-in for them. In addition, VA physicians and pharmacists prepare comprehensive written reviews that summarize recent published research on the safety and efficacy of drugs in specific drug classes. These reviews may be used to make recommendations on a drug's status within the formulary. For example, a 2003 review of oral bisphosphonates (typically used to treat osteoporosis) concluded that since Fosamax and Actonel "produce similar results . . . the VHA should consider these two drugs equivalent clinically, and choose one for use based on best value."[4]

The VA considers some classes "closed," that is, drugs in that class are only covered if they are listed on the formulary. Generally, only a few drugs in a "closed" class are listed on the national formulary. The VA justifies the exclusion of others on the grounds that they are therapeutically interchangeable – "equivalent in terms of efficacy, safety and outcomes" – to the drugs on the formulary. The VA can then obtain lower prices for on-formulary drugs through competitive contracts by commit-

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[1] "Comparison of Compounds on the Formularies of Medicare Prescription Drug Plans (PDPs) and the Department of Veterans Affairs Veterans Health Administration (VA) National and Regional Formularies," prepared for the Pharmaceutical Research and Manufacturers of America by Covance Market Access Services Inc., December 2006.

[2] Greg D'Angelo, "The VA Drug Pricing Model," The Heritage Foundation, 11 April 2007.

[3] GAO, "VA Drug Formulary: Better Oversight is Required, but Veterans Are Getting Needed Drugs," Report to the Ranking Member, Senate Committee on Veteran's Affairs, January 2001. Donna Young, "VA's 10-Year Journey to One Formulary Concludes," *American Journal of Health-System Pharmacy*, 64 (15 March 2007): 578–580.

[4] Marc C. Geraci, "Drug Class Review Oral Bisphosphonates in the Treatment of Osteoporosis," VHA Pharmacy Benefits Management Strategic Health care Group and the Medical Advisory Panel, September 2003.

ting to use them whenever clinically appropriate.[5] Most often, these are classes where multiple brand-name drugs are available, but few or no generic alternatives. Drugs in other classes may have restrictions, meaning that physicians are encouraged to prescribe certain "preferred" drugs in that class over others.[6] Such restrictions are used both to create leverage in negotiating prices and to restrict inappropriate use of certain drugs.

According to the VHA, drugs not listed on the national formulary may be prescribed through a non-formulary request process designed to ensure timely, evidence-based decisions. Non-formulary drugs may be approved for use by a patient if:

1. Formulary agents are contraindicated;
2. Formulary agents have caused adverse reactions;
3. All formulary alternatives have demonstrated therapeutic failure;
4. No formulary alternative exists; or
5. "The patient has previously responded to a non-formulary agent and risk is associated with a change to a formulary agent."

Through this process, drugs not listed on the VA formulary can be prescribed. An informal survey by the VA pharmacy benefit manager in 1998 found that "88 percent of waiver requests [for non-formulary medications] were approved."[7] Nevertheless, VA formulary compliance is very high. The VA estimates that overall use of drugs not on the formulary is about 5 percent. This high compliance, especially for the closed classes, is aided by the sense of buy-in by VA clinicians and the reliance on clinical evidence as a key component of the decision-making process. Adherence for a closed class sometimes reaches 90 percent within 3 months of a formulary change and over 98 percent within 6 months.[8]

Several studies over the past decade have asked whether the VA National Formulary too strictly limits the prescription drugs available to veterans. After a 1999 report by the House Committee on Appropriations raised such concerns, a mandated report by the Institute of Medicine, released in 2000, concluded that "the VA National Formulary is not overly restrictive, and the limited available evidence suggests that it has probably meaningfully reduced drug expenditures without demonstrable adverse effects on quality." The reviewers also found, however, that the National Formulary lacked "essential systems to assure that new drugs are expeditiously reviewed" and that more needed to be done to ensure "that a responsive process for assuring access to medically necessary exceptions to the formulary is consistently in place."[9]

In 1999 and 2000, the VA commissioned two independent surveys of VA prescribers' perceptions of the VA National Formulary. The first survey identified a subset of physicians who believed this formulary was more restrictive than most in the private sector or that it impinged on providing quality care to their patients. But nearly two-thirds thought they were able to prescribe needed drugs and that their patients could obtain nonformulary drugs when needed.[10] Respondents to the second survey also indicated general satisfaction with the formulary and agreed that it was important for containing costs and ensuring good value. Although they reported that roughly 90 percent of waiver requests for off-formulary drugs were approved, about one-third of the physicians indicated that approvals took 3 days or longer.[11] In 2001 the Government Accountability Office told the Congress that "prescribers reported that the national formulary generally contains the drugs their patients need or, when necessary, prescribers can usually get non-formulary drugs."[12]

In a 2005 report, economist Frank Lichtenberg concluded that the VA was tardy in its addition of newly FDA-approved drugs to the VHA formulary, and noted "that

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[5] GAO, "VA Drug Formulary: Better Oversight is Required, but Veterans Are Getting Needed Drugs."

[6] Institute of Medicine, *Description and Analysis of the VA National Formulary* (Washington: National Academic Press, June 2000).

[7] IOM, *Description and Analysis of the VA National Formulary.*

[8] Michael Valentino, "Overview of the VA Pharmacy Benefits Management Strategic Health Care Group (PBM)," presentation to the American Enterprise Institute, 19 January 2007.

[9] IOM, *Description and Analysis of the VA National Formulary.*

[10] Peter A. Glassman et al., "Physician Perceptions of a National Formulary," *American Journal of Managed Care* 7:3 (March 2001), pp. 241–251.

[11] Peter A. Glassman et al., "Physician Satisfaction with Formulary Policies: Is It Access to Formulary or Nonformulary Drugs that Matters Most?" *American Journal of Managed Care* 10:3 (March 2004), pp. 209–216.

[12] "VA Drug Formulary: Better Oversight is Required, but Veterans are Getting Needed Drugs."

only 19 percent of the drugs approved since 2000 were on the VHA formulary."[13] Lichtenberg attributed the use of older drugs in the VA formulary to a reduction in veterans' mean age of death, by 2.04 months. But Lichtenberg's report was rebutted by the VA's Michael Valentino in a 2007 presentation.[14] He offered evidence that veterans experienced greater life expectancies at birth than other populations. Arguing that "newer is not always better," he pointed out that "many 'new' drugs are actually 'me too' drugs" that are essentially the same as – and not necessarily more effective than – treatments already on the market. Valentino also noted that 23 new drugs (including some that Lichtenberg lists as not covered by the VA) were taken off the market for safety reasons between 1980 and 2005, and concluded, "what is the rationale for exposing patients to drugs with unknown risks, when there is little or no clinical advantage?" Valentino insisted that the "VA reviews all new molecular entities for consideration for national formulary listing in a timely fashion," and that it based its decisions on cost and efficacy data.

Comparing VA and Medicare Part D Plan Formularies

To compare the VA National Formulary with those offered by the Medicare Part D prescription drug plans, my colleagues and I focused on a pre-selected sample of 160 drugs representing more than half the prescription volume for Medicare beneficiaries. The sample includes all drugs in 14 drug classes, as well as other commonly prescribed drugs, and has nearly equal numbers of generic (n=76) and brand-name (n=84) medications.[15] For Medicare, our analysis covers 47 standalone prescription drug plans offered on a national or near-national basis in 2007, as well as two formularies offered in different regions by a group model HMO participating in the Medicare Advantage program. We considered the number of plans that listed a drug, whether the drug was placed on a generic, preferred, or specialty tier, and whether the drug was restricted through any utilization management tools (prior authorization, step therapy, or quantity limits). For the VA, the analysis considered whether a drug was listed on formulary and the yearly volume of prescriptions written for that drug.[16]

A simple count of the 160 sample drugs on the VA formulary suggests that it lists fewer drugs (82 drugs) than any of the national or near-national Part D plans (median number of drugs listed = 136; minimum = 99). However, there are key reasons that make this simple accounting misleading. First, veterans have unrestricted access to all drugs listed on the VA formulary and access to additional drugs if they seek authorization. By contrast, Part D plans include drugs on their formularies that may only be available to beneficiaries subject to utilization restrictions, such as prior authorization, step therapy, or quantity limits. In the VA system, patients only need to seek prior authorization or undergo step therapy for drugs not listed on the VA National Formulary.

The TNF Inhibitor class, which includes three expensive specialty drugs primarily used for treating rheumatoid arthritis (Enbrel, Humira, and Remicade), illustrates this dynamic. Neither the VA nor the median Part D plan covers any of these drugs outright. In the VA, the drugs are considered off formulary, but they are available when patients or their doctors request authorization. Most Medicare drug plans list these three drugs on formulary, but require prior authorization before the drug is actually covered. In these two situations, patients face a similar level of restricted access, but the formulary status is different.

Second, many Part D plans list drugs on a "non-preferred" tier with a higher level of cost sharing. This system creates a financial incentive for beneficiaries to adhere to their plan's formulary, even when their doctor may not know which drugs are preferred or not preferred. By contrast, the VA does not use tiers; cost sharing for any drug is limited to $8 for a month's supply for those patients subject to the co-

[13] Frank R. Lichtenberg, "Older Drugs, Shorter Lives? An Examination of the Health Effects of the Veterans Health Administration Formulary," Center for Medical Progress at the Manhattan Institute, October 2005.

[14] Michael Valentino, "Overview of the VA Pharmacy Benefits Management Strategic Health Care Group."

[15] For more details on our sample of drugs, see Jack Hoadley et al., "An In-Depth Examination of Formularies and Other Features of Medicare Drug Plans," Henry J. Kaiser Family Foundation, April 2006, and Jack Hoadley et al., "Benefit Design and Formularies of Medicare Drug Plans: A Comparison of 2006 and 2007 Offerings – A First Look," Henry J. Kaiser Family Foundation, November 2006.

[16] Data on whether a drug is on the VA National Formulary and its restrictions were obtained from the VA's Web site (January 2007 version). Information on the prescription volume was provided to the authors by the VA. The VA's formulary lists all drugs by chemical name; thus we assumed that when both a generic and a brand-name version of a particular chemical exist, only the generic version is listed.

payment. Because VA doctors use only the VA formulary, they can become familiar with its coverage; financial incentives are not needed to steer use.

Because of these system differences, it is most relevant to compare the VA's formulary to the list of drugs that are on a preferred tier in a Part D plan's formulary, without designations for either prior authorization or step therapy.[17] For the national and near-national plans, the median number of unrestricted on-formulary drugs is 104, compared to 136 when restricted drugs are included. By this criterion the typical Medicare plan formulary comes closer to the 82 drugs listed on the VA National Formulary (Table 1).

Table 1. Number of Drugs with Unrestricted Coverage, VA Formulary and Selected Medicare Plans, 2007

	All Drugs (N=160)	Generic Drugs (N=76)	Brand Drugs (N=84)
On VA Formulary	82	56	26
Median, 47 national Part D plans	104*	72	37
Minimum, 47 national Part D plans	80*	48	20
Maximum, 47 national Part D plans	149	76	73
Top 10 Part D plans, by 2006 enrollment			
AARP Medicare Rx Basic	112	75	37
Community Care Rx Basic	98	70	28
Humana/Complete	121	76	45
Humana/Enhanced	121	76	45
Humana/Standard	149	76	73
Medicare RX Rewards Value	117	76	41
Prescription Pathway Bronze	118	74	44
Silverscript (Caremark)	102	63	39
United Healthcare Rx Basic	97	73	24
Wellcare/Signature	94	74	20
Group Model Medicare Advantage Plans			
Kaiser Permanente, Northern California	77	45	32
Kaiser Permanente, Southern California	79	50	29

*Median and minimum for "all drugs" are measured directly and not the sum of the brands and generics values.

*Note: Unrestricted coverage is defined as coverage on a preferred tier with no prior authorization or step therapy requirements.

One view of the difference between the VA's formulary and those used by Part D plans is how they treat the generic drugs in our sample (Table 1). The typical Part D plan lists over 90 percent of generic drugs, and several of the ten most popular plans list all of the generics we studied. By contrast, the VA lists only 56 of 76 sample generic drugs. This reflects the different perspective of those designing these formularies. The VA chooses preferred drugs among competing generics based on a combination of clinical evidence and price. By contrast, Part D plans have incentives to list on formulary most or all of the generics in a particular class. Lacking

[17] When a drug has a quantity limit, we do not treat that as a restriction. Some plans designate large numbers of drugs with quantity limits, apparently to restrict the dispensing of prescriptions of more than 30 days.

any close relationships with prescribing physicians, they must rely on enforcement at the pharmacy to encourage use of one particular generic over another. Doing so risks alienating their enrollees for minimal financial gain and may discourage enrollment if drugs are listed as off-formulary on the Medicare's online Drug Plan Finder.

As noted above, the approach to formulary design in an integrated health plan is more like the VA system than other Part D plans. It is not surprising, therefore, that Kaiser Permanente formularies were similar in scope to the VA formulary (Table 1). In both of its California regions, Kaiser Permanente listed slightly fewer sample drugs on formulary (77 and 79) than the VA National Formulary. Like the VA, the Kaiser plans are more likely than other Part D plans to omit generic drugs from their formularies.

Comparisons at the Drug Class Level

Comparisons between the VA National Formulary and the Part D plan formularies vary considerably by drug class (Table 2). One reason for the variation is that some drug classes (e.g. beta blockers) consist mostly of generic drugs. Most Part D plans list nearly all generics on formulary, whereas the VA is more likely to omit generic drugs from its formulary for such classes. Specific program rules also affect the comparisons. For example, Part D plans include more anti-depressants at least partly because Medicare guidelines require that nearly all unique anti-depressants be listed on formulary, although the guidelines do not require that coverage be unrestricted.

Table 2. Formulary Listings by Class, VA and Part D Formularies, 2007

Drug Class	Drugs Studied	VA National Formulary	Median, 47 National Plans*	KP Northern CA	KP Southern CA
Anti-Dementia Agents	6	5	4	3	3
Anti-Depressants	30	18	23	24	24
Beta Blockers	15	7	14	6	9
Calcuim Channel Blockers	9	5	6	4	3
Cholesterol Agents	18	7	11	4	5
Diabetes Agents	16	5	12	6	8
Proton Pump Inhibitors	6	1	2	2	2
Hormonal Agents	12	6	4	7	6
Renin-Angiotensin	18	8	10	3	3
TNF Inhibitors	3	0	0	3	3
Other Common Drugs	27	20	22	14	12
TOTAL, SELECTED DRUGS	160	82	104	77	79

*Drugs listed on a generic or preferred tier and without prior authorization or step therapy restrictions. Note that the median value for the total is not the total of the class medians.

The pattern is similar for the Kaiser Permanente formularies, but the details are different. Kaiser's formularies, for example, list fewer drugs in categories such as anti-cholesterol agents or the renin-angiotensin drugs used to treat hypertension. But Kaiser lists more anti-depressants than the typical Part D plan. Kaiser also lists more drugs without restriction in the TNF inhibitor class than either the VA or the typical Part D plan, because they do not require prior authorization for these drugs.

The Class of Cholesterol Drugs

The contrasting ways that formularies work in the VA compared to the stand-alone Part D plans can be illustrated with the class of cholesterol drugs. The VA's coverage of cholesterol agents has been criticized because the formulary does not list some popular anti-cholesterol drugs such as Crestor and Lipitor, while the majority of national Part D plans list them without restrictions.[18] As shown in Table 2, the typical Part D plan lists 11 of the anti-cholesterol agents in our sample, whereas the VA lists 7 drugs and Kaiser Permanente lists just 4 in one region and 5 in another.

[18] Deroy Murdock, "VA Program No Model for Helping Americans Buy Medications," *Deseret News*, 31 December 2006.

Whenever possible, the VA suggests that a "high potency" formulary statin should be the first-line treatment prescribed for the patient. If he or she fails to meet clinical goals on that drug, physicians are advised to consider a second-line therapy (such as niacin or non-formulary Zetia) or a switch to a non-formulary statin, such as Lipitor.[19] These guidelines mean that non-preferred or even non-formulary drugs are recommended and accessible to veterans, and they may be prescribed in greater numbers than their on-formulary or unrestricted counterparts. In fact, as Table 3 shows, there is more utilization of Zetia, considered a second-line therapy not listed on formulary, than the two on-formulary drugs in the Bile Acid Sequestrants group. Similarly, prescribing of Lipitor, another second-line therapy that is not on formulary, is higher than for Lescol, one of the on-formulary statins.[20]

Table 3. Formulary Listing of Cholesterol Agents, 2007

Drug*	Generic Name	On VA Formulary?	# of 47 Part D plans with unrestricted coverage	VA Utilization FY 2006
Bile Acid Sequestrants				
CHOLESTRYAMINE	CHOLESTRYAMINE	Y	46	52,249
Welchol	COLESVELAM	N	20	4,714
Colestid	COLESTIPOL	Y	18	168,976
Cholesterol Absorption Inhibitors				
Zetia	EZETIMIBE	N	36	369,783
Fibrates				
Tricor	FENOFIBRATE	N	37	130,181
GEMFIBROZIL	GEMFIBROZIL	Y	47	1,771,658
Nicotinic Acid				
Niaspan ER	NIACIN	Y	41	1,258,306
Omega-3 Fatty Acids				
Omacor	OMEGA-3 ACID	N	13	827
Statins				
Lipitor	ATORVASTATIN	N	34	711,138
Lescol	FLUVASTATIN	Y	8	500,954
Altoprev ER	LOVASTATIN	N	9	12
LOVASTATIN	LOVASTATIN	Y	47	1,424,081
Mevacor	LOVASTATIN	N	4	376,688
Pravachol	PRAVASTATIN	N	1	56,255
PRAVASTATIN	PRAVASTATIN	N	33	**
Crestor	ROSUVASTATIN	N	33	144,341

[19] "Ezetimibe (Zetia®) for Nonformulary Use," VHA Pharmacy Benefits Management Strategic Healthcare Group and the Medical Advisory Panel, updated January 2007.

[20] After this analysis was completed, changes were made to the VA National Formulary's treatment of statins in response to FDA approval of generic versions of Pravachol and Zocor.

Table 3. Formulary Listing of Cholesterol Agents, 2007—Continued

Drug*	Generic Name	On VA Formulary?	# of 47 Part D plans with unrestricted coverage	VA Utilization FY 2006
SIMVASTATIN	SIMVASTATIN	Y	45	**
Zocor	SIMVASTATIN	N	5	16,487,514

*Drug names in all capital letters are generic drugs.
**Data are not available for the newly approved generic versions of pravastatin and simvastatin. Previously, the brand version of Zocor was on formulary.

Comparative effectiveness reviews of clinical evidence have led to a similar conclusion to that of the VA. The Consumer Reports "Best Buy Drugs" report, based on research by the Drug Effectiveness Review Project, recommends use of one of three generic statins, with Lipitor as an alternative for patients who have had a heart attack or acute coronary syndrome together with highly elevated LDL.[21] Among the 47 national and near-national Part D plans, 34 list Lipitor and 33 list Crestor, while nearly all list generic drugs lovastatin and simvastatin.

Another factor that affects the formulary comparisons is the Medicare Program's guidance requiring that Part D plans list on formulary at least one drug in each subgroup of cholesterol drugs, although plans may use coverage restrictions. The VA has no such mandatory coverage requirement. Because Zetia and Omacor are the only drugs in their subgroups, Part D plans must list them, whereas the VA formulary does not. Nevertheless, shown in Table 3, not all Part D plans have unrestricted coverage of these drugs. The VA, which recommends Zetia as a second-line therapy, filled about 370,000 prescriptions for the drug.

Conclusions

An objective comparison of unrestricted coverage by Medicare Part D plans to the VA National Formulary shows that the VA formulary is modestly smaller than the typical Part D plan formulary and about the same as formularies used by Kaiser Permanente. But formulary size is not the same as access to drugs. This small gap largely reflects the difference between integrated and non-integrated health systems and the resulting approaches to ensuring access.

The VA National Formulary is closely tied to its prescribing system. Like a staff-model or group-model HMO, physicians in the VA system participate in creating the formulary and commit to prescribing from it when it meets their patients' needs. Patients in both of these integrated healthcare systems are less likely than other types of Part D or private health plans to receive a prescription, only to be told later that it is not covered or covered at a much higher price than a more preferred drug. The incentive in integrated systems is for physicians to prescribe from the formulary when they can, but it is a relatively straightforward process to obtain authorization for any drug that is not on the formulary. By contrast, physicians treating patients in non-integrated systems face a variety of formularies for the different plans in which their patients are enrolled, and they are unlikely to prescribe according to each patient's formulary unless the plan or patient points out which drugs are preferred. It is essential when making comparisons with regard to access to drugs between the VA and other plans to keep these differences in mind.

A full comparison of access to prescription drugs between the VA system and other health systems would require more extensive studies, such as surveys or clinical outcome studies. Nevertheless, this comparison of Medicare Part D plan formularies to the VA formulary lends support to the conclusion that veterans maintain good access to prescription drugs through the VA National Formulary.

[21] http://www.bestbuydrugs.org/drugreport__DR__Statins.shtml

Prepared Statement of Frank R. Lichtenberg, Ph.D.,
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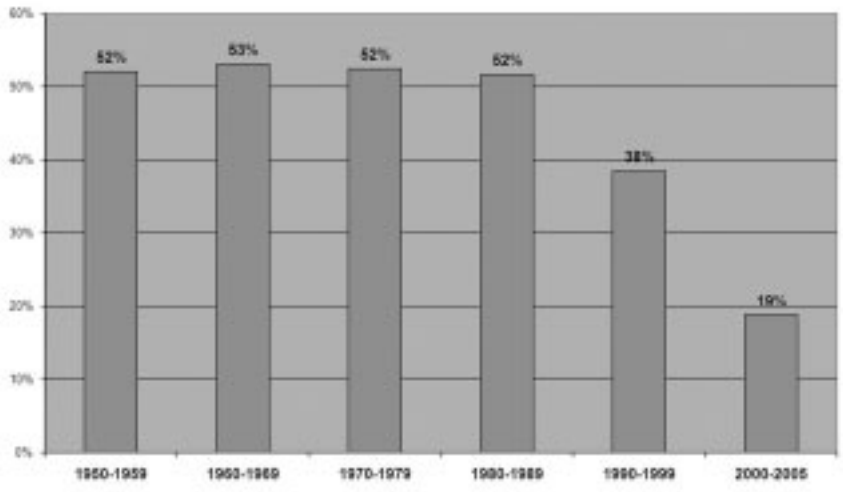
National Bureau of Economic Research

Access to new drugs in the Veterans Health Administration

Access to medical innovations → longevity and health

- Research that I and other economists have performed indicates that **access to medical innovations—new drugs, medical procedures, and devices—is one of the most important determinants of longevity and health.**
- Four years ago I performed a study that examined access to new drugs under the pharmacy benefits management system of the Veterans Health Administration. Since 1997, the VA National Formulary has played a key role in that system.
- The fractions of drugs approved in the 1950s, 1960s, 1970s, and 1980s that were on the 2005 VA National Formulary were almost identical: 52–53 percent.
- However, **only 38 percent of the drugs approved in the 1990s, and 19 percent of the drugs approved since 2000, were on the VA National Formulary. Only 22 percent (17) of the 77 priority-review drugs approved since 1997 were on the 2005 National Formulary.** (Figure 1)

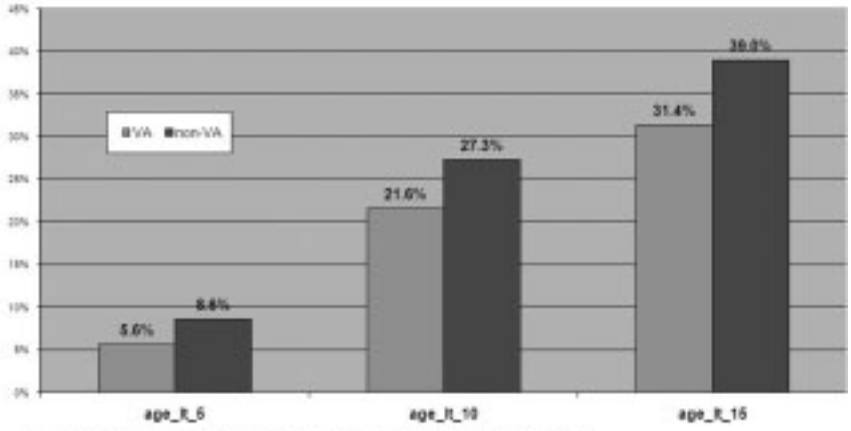
Figure 1
Percent of drugs on 2005 VA National Formulary, by decade of FDA approval



Older drugs used by VA patients

- The drugs used in the VA health system during 1999–2002 were older than the drugs used in the rest of the U.S. healthcare system. For example, the percentages of VA and non-VA prescriptions for drugs less than 5 years old were 5.6 percent and 8.6 percent, respectively, and the percentages for drugs less than fifteen years old were 31.4 percent and 39.0 percent. (Figure 2)

Figure 2
Percent of 1999-2002 VA and non-VA prescriptions for drugs less than 5, 10, and 15 years old



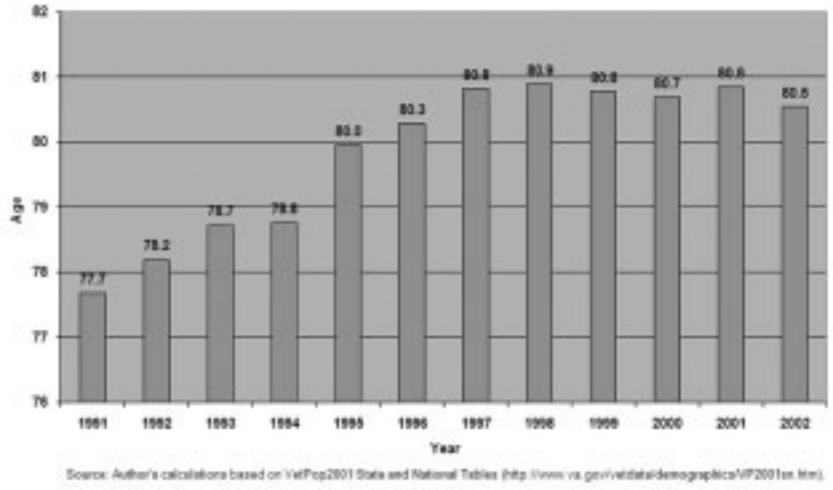
Percentages based on 10,495 VA prescriptions and 723,264 non-VA prescriptions.
All three differences in percentages are significant (p-value < .001).

- The percent of drugs less than 10 years old increased by 1.4 percentage points per year in the non-VA sector, and by 0.6 percentage points per year in the VA sector. The percent of drugs less than 15 years old increased by 1.9 percentage points per year in the non-VA sector, and had virtually no increase in the VA sector.
- These **estimates are consistent with the hypothesis that implementation of the VA National Formulary beginning in 1997 reduced utilization of new drugs in the VA healthcare system.**

Older drugs → reduced longevity, higher utilization of hospitals and nursing homes

- I present estimates of the impact of utilization of new drugs on longevity, based on annual data on Medicaid drug utilization and mortality by State, disease, and year, for all 50 States during the period 1991–2001.
- The estimates imply that **use of older drugs in the VA system reduced mean age at death of its patients by 0.17 years, or 2.04 months. The per-patient value of this reduction in longevity may exceed $25,000.**
- I use demographic data published by the VA to compute the life expectancy of veterans before and after the National Formulary was implemented. **Veterans' life expectancy increased substantially before the National Formulary was introduced (during 1991–1997), but did not increase, and may have even declined, after it was introduced (1997–2002).** (Figure 3)

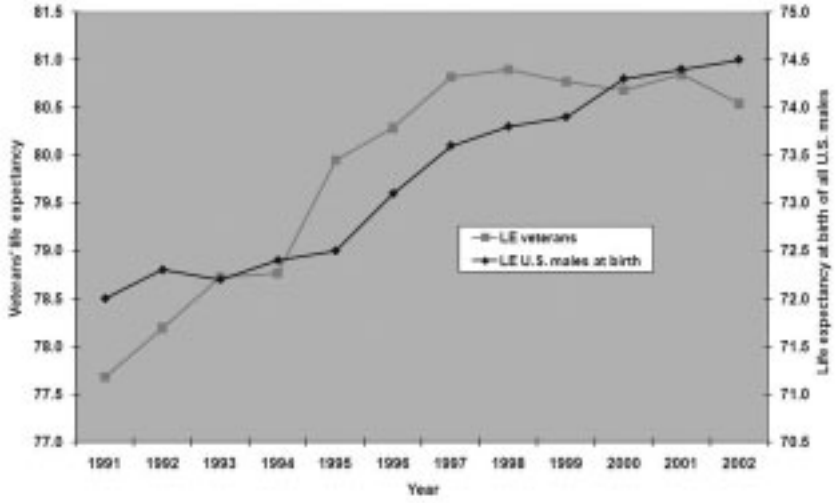
Figure 3
Life expectancy of veterans, 1991-2002



Source: Author's calculations based on VetPop2001 State and National Tables (http://www.va.gov/vetdata/demographics/VP2001sn.htm).

- The life expectancy at birth of all U.S. males increased after as well as before 1997, although the rate of growth declined by about a third. (Figure 4)

Figure 4
Veterans' life expectancy vs. life expectancy at birth of all U.S. Males



- **Implementation of the VA National Formulary is likely to have increased utilization of hospitals and nursing homes.** I estimate that if the age of the drugs used by the Medicare population were increased to match that used in the VA health system, the increase in hospital, home healthcare, office-visit, and nursing-home expenditure among the elderly would be about $5.1 billion per year.

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Prepared Statement of Richard F. Weidman, Executive Director for Policy and Government Affairs, Vietnam Veterans of America

Chairman Michaud, Ranking Member Brown and distinguished Members of the Subcommittee, on behalf of National President John Rowan, our Board of Directors and Members, I thank you for giving Vietnam Veterans of America (VVA) the opportunity to testify today regarding the "Is the VA Meeting the Pharmaceutical Needs of Veterans? An Examination of the VA National Formulary, Issues of Patient Safety, and Management of the Pharmacy Benefits Program."

In May of this year VVA wrote to Chairman Filner as part of VVA's answer to his question about issues that need to be addressed by the House Veterans Affairs Committee VVA responded with five issues, one of which is described below:

> **Pharmacy Service**—the formulary is much too restrictive (and much more restrictive than either DoD or Medicare) on the theory that they are going to save a lot of money on medications. However, they often save pennies and spend big dollars because they scrimp on medications that could have prevented very costly acute care in-patient stays. The method of evaluating pharmacists needs to be dramatically changed from how much in "savings" they produce in comparison with the national average (which becomes a "race to the bottom") to how much did what they do in cooperation with the medical staff at a given VA Medical Center to promote healing and wellness, and reduce in-patient acute care stays in the hospital, and/or to prevent secondary conditions from developing.

The crux of this issue remains the same some 5 months later.

In lay terms, VVA believes that what we have at the Veterans Health Administration (VHA) of the U.S. Department of Veterans Affairs (VA) is a mentality that tries to reduce front end costs (e.g., pharmaceutical costs) which they call "cost avoidance," without regard to overall impact either on the health of the individuals concerned or the overall cost impact on the system. In other words, they save some money by artificially limiting the number and type of pharmaceuticals that are generally available to clinicians at the VHA facilities, regardless of whether that in the medium to long-run it causes veterans to have secondary conditions. This practice is justified on the basis of "cost effectiveness" within the context of just pharmaceuticals alone, without regard for the rest of the medical setting.

It is ironic that the Research & Development section of VA is holding a conference tomorrow in Washington to look at "comparative effectiveness" in research and in other applications. While models such as evidence based medicine has a real place, and has been of significant use especially in treating psychiatric problems, it has all too often been misapplied to practical allocation of resources, such as the way in which VHA has implemented the formulary at VHA. VVA would suggest that "comparative effectiveness" be applied to the overall healthcare system, in such a way as to focus on "comprehensive effectiveness."

Frankly, "comparative effectiveness" has been misapplied to the VA formulary in such a way that it is a "race to the bottom." Furthermore, when you are sick, Mr. Chairman, you are not necessarily in the majority part of the group that inexpensive "drug A" worked for just as well as the more expensive (usually copyright/patent protected) "drug B" when the two were tested for efficacy against each other. The decision of which to offer should be a clinical decision by the physician in concert with the patient, as to what is going to work the best for the individual patient. The practical tools available to a veterans' physician should not be artificially limited by what is listed on the VA formulary.

We know if something is not on the formulary, it is very difficult, if not impossible, for most patients of that physician to get it. When we raise this issue, VA retorts that any physician can order any Food & Drug Administration (FDA) approved medication, whether it is on the formulary or not. While theoretically a physician can secure medications not on the formulary, as a practical matter it is inordinately difficult and time consuming to do so, and if a physician does it too often, they are "counseled" by their supervisor.

VVA has made the point to three of the most recent Undersecretaries for Health at VA, and to Secretary Peake when he was in office, that the VA National Formulary decision-making process lacks transparency and public input that would cause them to have to justify keeping something off of the formulary as opposed to putting something on the formulary. This is just not right, and no way to make public "life or death" policy decisions. This entire process needs to play out in the open, in the sunshine, where it can clearly be seen by the public and by clinicians what is being done and why it is being done. That is not the case at VHA today.

The VA formulary has just over 1,300 drugs while the average Medicare Part D formulary has more than 2,000 drugs. Only 38 percent of the drugs approved by the FDA in the 1990s, and 19 percent of the drugs approved since 2000, are on the VA National Formulary. It is clear to us that the VA has a policy bias toward generics and those drugs whose patents have expired, making them cheaper. This is despite the fact that the VA has the best price in the world on pharmacy medications.

While we do not believe that "newer" is always better, that is a clinical decision that the veteran's individual physician should be making, and not "the green eye shade" fiscal guys in a back room somewhere.

The restrictive VA formulary could have a deleterious effect on the longevity and quality of life of veterans. Just one example of this is how slow VHA was to add the long-lasting insulin to the VHA formulary (and then only after significant pressure from VVA and from this Committee), and the fact that many of the most effective treatments for diabetes, many of which have appeared on the market since 2000, are still not available on the VA formulary. The average beneficiary has better access to newer diabetes and heart disease drugs through Medicare Part D and Medicaid than does the average veteran through the VA. This is just wrong, and needs to be fixed by broadening the VA formulary, and by opening up this whole process.

The toughest things to get on the VA formulary of all are the most innovative "new molecular entities" almost all of which are still under patent, and therefore avoided by the VA decisionmakers. In this instance there is apparently an evidence based process, but it can be (and often it is) vetoed by the pharmacy people strictly on the basis of the cost of the medication, and not by any part of an overall decision as to what is best for the veteran's overall health, nor the like total cost to the medical system of NOT providing this medications to veterans who would be helped by it.

By restricting access to innovative drug therapy for chronically ill veterans, VVA believes that the overly restrictive VA formulary may result in less than optimal health outcomes. Said another way, it is our belief that many of the VA Medical Centers are not doing such a great job of controlling the measures of diabetes A1C, partly because of the restrictive policies on medications. This results in "spikes" that are what cause the secondary conditions and/or very costly inpatient hospitalization stays in some of the more than a million diabetics being treated by VA. For this reason, it also results in the veteran developing secondary conditions, which are also service connected and result in higher monthly payments. But, obviously, the key thing here is the diminishment of the quality of life for the individual veteran.

While the 2000 Institute of Medicine (IOM) study of the then newly implemented (1997) VA National Formulary ... "found that the VA National Formulary is not overly restrictive, and the limited available evidence suggests that it has probably meaningfully reduced drug expenditures without demonstrable adverse effects on quality."

However, the IOM report findings continue: "The (IOM VA Formulary Study) Committee also concluded that there are manifold opportunities to improve the

management of the formulary system used by the VHA. The National Formulary lacks essential systems to assure that new drugs are expeditiously reviewed for inclusion, and that a responsive process for assuring access to medically necessary exceptions to the formulary is consistently in place system-wide, that therapeutic interchange is accomplished in a flexible and consistent way, sensitive to patient risk, across the far-flung VHA system, and that views of critical constituencies of both providers and patients are represented in the management of the National Formulary . . .''

Perhaps most troubling, the (IOM) Committee found ''a dearth of information to evaluate the full impact of the National Formulary on veterans health and satisfaction, and on the VHA.'' That remains the case today because the VA process takes place in the back room, out of public view.

Since the time of the IOM Study of the VA National Formulary, the VA Formulary and Formulary process has only grown more restrictive and little has been done to address the concerns expressed in the IOM study. Individual Veterans Integrated Services Network (VISN) formularies have been eliminated in favor of only a consolidated VA National Formulary.

The VA Formulary process involves internal Pharmacy and Medical expertise through its own Medical Advisory Panel (MAP) and is cross connected to the Department of Defense Pharmacoeconomic Center (DoD PEC) and Indian Health but does not have outside professional or beneficiary interest represented, such as the Veteran Service Organizations, or professional pharmacy and pharmacists organizations, or advocacy groups like the American Diabetes Association. Appropriate national level professional organizations that would best represent the patient as relates to safe and appropriate medication use, could include representation from professional organizations such as the American Pharmacists Association (APhA), American Society of Health-System Pharmacists (ASHP), Academy of Managed Care Pharmacy (AMCP), and American Society of Consultant Pharmacists (ASCP), as well as other professional medical societies.

The lack of transparency and insular nature of the VA formulary decision-making process is problematic and leaves unanswered questions about access to care, chronic disease care, criteria use in reaching decisions (e.g., costs versus long-term clinical effectiveness). VA should publish specific drug decision-making criteria, including the therapeutic category review schedule, decision-making process, Pharmacy and Therapeutics Committee and Medical Advisory Panel members, meeting schedules, and discussions of specific decisions. In addition, the public should have an opportunity to submit information to the VA Pharmacy and Therapeutics Committee in preparation for each decision meeting.

The VA formulary decision-making process should also include a VA Pharmacy Beneficiary Advisory Committee as does the Department of Defense TRICARE Uniform Formulary process. For example, the Department of Defense/TRICARE publically announces in advance its therapeutic class review schedule, the specific drugs for review, and the criteria for comparing different drugs. The DoD Pharmacoeconomic Center (PEC) receives pricing and clinical data from the public including pharmaceutical companies which are considered by the DoD Pharmacy and Therapeutics (P&T) Committee. The DoD publishes on its Web site (http://www.pec.ha.osd.mil/) the recommendation of the P&T Committee, the rationale, and summary of the data considered.

These recommendations are then reviewed by a DoD Beneficiary Advisory Panel (BAP; http://www.tricare.mil/pharmacy/bap/) composed of non-government beneficiary, professional and patient advocacy organization representatives, TRICARE contractors, and others. These meetings are also announced in advance, open to the public, and the results are published on the PEC Web site. The P&T Committee and the BAP recommendations are then forwarded to the Director of the TRICARE Management Activity for final decision. In most cases, newly FDA-approved prescription medications are available from TRICARE network pharmacies and the mail-order pharmacy program shortly after they become commercially available. Furthermore, the public has the opportunity for input at each step in the decision-making process, and it is transparent.

Conversely, the Department of Veterans Affairs National Formulary decision-making process lacks transparency and opportunity for public input. This results in major disadvantages for VA patients and the quality of VA healthcare. It can be argued that the overly restrictive VA formulary as it stands today is significantly distorting the practice of medicine at the VA, to the detriment of the health of veterans who seek care there.

Recommendations:

Optimally, the Congress will pass a law mandating an open and transparent process that is modeled on the law for DoD/TRICARE, and is at least as open and transparent a process (if not more so) than the DoD procedure. The DoD process automatically includes all medications approved by the FDA. It is up to managers to justify restricting access to a medication by removing it from the formulary, and this has to play out in a public setting with significant input from advocacy groups, medical societies, and other interested parties. VA should do no less for our veterans once they take off the uniform.

Short of this much needed comprehensive overhaul or transformation of the VA formulary, or perhaps while the Committee is working to draft and secure passage of this legislation, VVA recommends the following steps be taken immediately by Secretary Shinseki:

Change the performance evaluation criteria for Chief pharmacists to measure his or her contribution toward the overall wellness of the patients at a particular Medical Center. There are currently no such metrics in place, but they can be developed and these contributions measured, just like almost anything else. (Currently the pharmacists are rewarded by how much "cost avoidance" they can achieve in comparison with the national mean. This, of course, means that it is a "race to the bottom." It is a testimony to the professionalism and commitment to good medicine by the pharmacists that, given the way the system is set up, with the emphasis on cost containment/cost reduction, that so many veterans do get the right medication in the right amount when they need it.)

The VA P&T Committee meeting schedule, therapeutic categories to be reviewed, and review criteria should be publically announced well in advance of P&T meetings.

The VA P&T Committee should establish a procedure to accept and consider public input for these Formulary meetings.

The VA P&T Committee should publish its recommendations made in the last decade with rationale for the conclusions and recommendations of the Committee.

The Secretary of Veterans Affairs should establish a Beneficiary Advisory Committee (BAC) of representatives from a representative sampling of major veterans, patient advocacy, and healthcare professional groups with the responsibility and authority to make recommendations on the decisions of the VA P&T Committee including addition, deletions, clinical use criteria, and preauthorization requirements on drugs on the VA National Formulary.

Meetings of the VA Formulary Beneficiary Advisory Committee should be open to the public and the minutes and considerations of all BAC recommendations published on the VA P&T Committee Web site in a timely manner.

Like the DoD Beneficiary Advisory Panel, the VA Formulary Beneficiary Advisory Committee should include at least 12–15 members and have the opportunity to make Recommendations prior to final decision on VA National Formulary changes and other pharmaceutical issues. At least two of the following organizations should be included in the membership of the VA Beneficiary Advisory Committee, the American Pharmacists Association (APhA), American Society of Health-System Pharmacists (ASHP), Academy of Managed Care Pharmacy (AMCP), and American Society of Consultant Pharmacists (ASCP).

The VA Formulary Beneficiary Advisory Committee should have the authority to recommend to the VA drug categories and new drugs to be reviewed, changes to the criteria for use, clinical guidelines, restrictions on use, etc.

The Veterans Health Administration should be required to consider the recommendations of the VA Formulary Beneficiary Advisory Committee prior to making final decisions on VA Uniform Formulary including addition, deletions, clinical use criteria, and preauthorization requirements.

Conclusion

The Secretary of Veterans Affairs could do some, all, or most of the nine steps outlined here above within the scope of his authority. However, there will be stiff resistance on the part of VHA officials who like the status quo. All too often, some seemingly do not believe that they should be answerable to anyone outside of that closed system, much less individual veterans or veterans' service organizations. These folks will have millions of reasons not to change, and perhaps so will some at the Office of Management & Budget (OMB). They also have their own constituencies around Washington who will tell the Secretary that it is "just too expensive" to provide expensive drugs to veterans. These individuals have had years of practice in "push back" to prevent any significant change being accomplished without legislation passing the Congress.

It is our belief that the time is right for this Subcommittee to take the lead in creating a statutorily directed formulary that is inclusive as a starting point, that is totally transparent, and that has to take into account input from stakeholders, both medical professionals and advocates outside of government. The VA continues to have great "bargaining power" to secure the best possible prices on each and every medication, and we believe that the private sector will be reasonable in this regard. In any case, it is impossible to say "Care Second to None" until we clean up this major problem with the VA formulary.

If we are going to assist the President to achieve transformation of the VA for the 21st century, then there is no better place to start than ensuring full transparency in the VA formulary, and a presumption of inclusion of all FDA approved medications. And, for that, we need bi-partisan legislation and the strong leadership from this Subcommittee on this issue.

Thank you for your leadership in holding this hearing on a crucial subject, Mr. Chairman. I will be pleased to answer any questions, and look forward to working with you and your colleagues to greatly improve this vital service to veterans.

Prepared Statement of William Ray Bullman, M.A.M.,
Executive Vice President, National Council on Patient Information and Education, Bethesda, MD

Good afternoon Mr. Chairman and Members of the Subcommittee. I am Ray Bullman, Executive Vice President of the National Council on Patient Information and Education (NCPIE). I've been asked to testify this afternoon relative to NCPIE patient medication safety efforts and best practices or innovative means that NCPIE coalition Members utilize to enhance medication safety.

I would note at the outset that NCPIE does not focus specifically on formulary issues. Yet, recognizing the role and impact that formulary decision-making ultimately plays downstream on patient—healthcare provider communication, informed decision-making about therapy choice and what medication is prescribed or recommended and why, and ultimately—to what extent patients effectively self manage their medication therapy, NCPIE is pleased to help support the work of the Subcommittee this afternoon and moving forward. Additionally, I would point out that NCPIE educational messages and materials are motivated by what we refer to as the **"3Rs" for Safe Medicine Use**. They are:

- **Risk**–recognize that all medicines (prescription and nonprescription) have risks as well as benefits; and you need to weigh these risks and benefits carefully for every medicine you take.
- **Respect**–respect the power of your medicine and the value of medicines properly used.
- **Responsibility**–take responsibility for learning about how to take each medication safely. Being responsible also means following this important rule: when in doubt, ask first. Your healthcare professional can help you get the facts you need to use medicines correctly.

These **"3 Rs"** are likely similar to motivators for healthcare providers within the VA as they make evidence-based formulary decisions and VA pharmacists, as they collaborate with members of the VA's interdisciplinary healthcare team, and as they counsel patients about safe and appropriate medicine use. As such, NCPIE is pleased to help support VA pharmacists, a subset of the Nation's medication experts, as they work collaboratively within the VA pharmacy system on what NCPIE refers to as the "Medicine Education Team," to help optimize medication therapy and to minimize patient risks.

About NCPIE

NCPIE was established in October 1982 as a non-profit organization. Its founding Chair was Congressman Paul G. Rogers (who served 24 years in the U.S. House of Representatives representing West Palm Beach, FL, and during his tenure was referred to as "Mr. Health" for his leading role in passing dozens of measures promoting healthcare and the environment). The late Honorable Congressman Rogers served as NCPIE's Chair for 16 years.

NCPIE is a diverse coalition of organizations working to stimulate and improve communication of information on the appropriate use of medicines to consumers and healthcare professionals. NCPIE develops programs, provides educational resources, issues research reports, conducts special issues meetings and multi-media campaigns, such as our annual **"Talk About Prescriptions" Month** every October. As such, NCPIE's activities are guided by three common values: 1) to represent a wide

spectrum of organizations serving the public health through educational and advocacy programs; 2) to empower consumers to be more informed about and active in decisions affecting their use of medicines; and 3) to be a catalyst and convener for the development of new, useful, and scientifically accurate information about medicine use that is disseminated in multiple formats to a wide range of audiences.

What makes NCPIE unique, besides its long-term focus on the appropriate use of medicines, is the depth and breadth of its national coalition of nearly 100 organizations committed to providing patients with useful and appropriate medicine information. The NCPIE coalition includes: consumer organizations; patient advocacy groups, and voluntary health agencies; organizations representing healthcare professionals and health educators; schools of pharmacy; State and Federal Government agencies; health-related trade associations; national and international private sector companies including pharmaceutical manufacturers, patient information/database companies, and managed care organizations.

NCPIE is based in Bethesda, Maryland. J. Leonard Lichtenfeld, M.D., representing the American Cancer Society, currently serves as NCPIE's Chairperson.

Patient Medication Safety Issues/Current and Ongoing NCPIE Programs

NCPIE is one of the original patient safety organizations, addressing safe and appropriate medicine use through the identification, development, and dissemination of educational messages and resources to promote safe and appropriate medicine use. NCPIE also convenes and participates in ongoing and ad-hoc external collaborations and issues-driven project partnerships, striving to address a wide range of potential medication safety (safe use) issues, as described below:

Safety Issues Related to Communicating Risk via Written Consumer Medicine Information—NCPIE, in 1996, at the request of then HHS Secretary Shalala, participated in the development of a **10–Year Action Plan for the Provision of Useful Prescription Medicine Information. The Action Plan,** which included criteria for quality improvements for both clinical content and the design, layout, and readability of written medicine information leaflets conveyed by community pharmacies with every retail prescription, sunset in December 2006. The Food and Drug Administration as the lead agency responsible for assessing to what extent **Action Plan** quality improvements were achieved by the private sector during this 10-year period, is conducting a 2-day workshop later this week to obtain key stakeholder input on proposed new prototypes for such useful written information and to seek input on a research agenda to ensure consumer input on the development, design, and testing of such written information. NCPIE is participating in the workshop as a reactor panelist.

Safety Issues Related to Medication Nonadherence—Although the challenge of poor adherence has been discussed and debated for at least three decades, these problems have, until recently, generally been overlooked as a major healthcare priority. NCPIE has since 1995 called for national action to address this major public health problem that has recently been estimated to cost the U.S. economy over $290 billion annually—or *13 percent of total healthcare expenditures* (New England Health Care Institute, July 2009). Consider:

- Nearly 3/4 of Americans report they don't take their medications as directed;
- One in three never fill their prescriptions;
- For common chronic conditions such as diabetes and hypertension, proper adherence averages only 50–65 percent;
- Three–69 percent of medication-related hospital admissions are linked to poor adherence.

Failure to follow medication regimes is especially harmful to people with chronic health conditions. When those with chronic conditions fail to follow their medication regimen, they risk decreased productivity, a lesser quality of life, a more rapid progression of their condition, complications, hospitalization, and even death. Employers are seeing billions of dollars lost to chronic condition-related absenteeism and *presenteeism* (when employees report for work, but do not function at full capacity). It is estimated that diabetes accounts for 120 million work days lost every year to presenteeism.

In 1995, NCPIE released the referenced report, **"Prescription Medicine Compliance: A Review of the Baseline of Knowledge,"** which outlined the health consequences of nonadherence and defined key factors contributing to poor medication adherence. The report included an overview of strategies to enhance adherence, along with implementation tools and materials.

In August 2007, NCPIE released its second report, **"Enhancing Prescription Medicine Adherence: A National Action Plan."** This referenced report was released as a renewed nationwide call to action for improving medication adherence through patient information and education, health professional intervention, ex-

panded research, and supportive government policies. The report includes 10 recommendations for action that cross-cut the continuum of care—from diagnosis through treatment and follow-up patient care and monitoring. The report is available for download at www.talkaboutrx.org.

1. Elevate patient adherence as a critical healthcare issue.
2. Agree on a common adherence terminology that will unite all stakeholders.
3. Create a public/private partnership to mount a unified national education campaign to make patient adherence a national health priority.
4. Establish a multidisciplinary approach to compliance education and management.
5. Immediately implement professional training and increase the funding for professional education on patient medication adherence.
6. Address the barriers to patient adherence for patients with low health literacy.
7. Create the means to share information about best practices in adherence education and management.
8. Develop a curriculum on medication adherence for use in medical schools and allied healthcare institutions.
9. Seek regulatory changes to remove roadblocks for adherence assistance programs.
10. Increase the Federal budget and stimulate rigorous research on medication adherence.

Safety Issues Related to Prevention of Medication Abuse Among Teens—While the use of tobacco, alcohol and illicit drugs is declining overall, a new threat is emerging; more teens are abusing prescription drugs than any illicit drug, except marijuana. The misuse and abuse of prescription medications—the very same drugs used to legitimately relieve pain, and treat conditions like anxiety, depression, sleep disorders, or ADHD in some people—is a growing and under-recognized problem that puts young lives at risk.

- One in 5 teens (or 4.5 million) has deliberately abused these drugs.
- One in 3 teens surveyed says there is "nothing wrong" when using prescription drugs "every once and a while."
- Every day, 2,500 youth (12–17) abuse a prescription pain reliever for the very first time.

NCPIE, with contract support from the Substance Abuse and Mental Health Services Administration (SAMHSA), and input from a project advisory team of over a dozen national organizations involved in drug abuse prevention and teen health, has developed two collaborative educational campaigns to promote prevention of prescription medicine abuse among teenagers:

- ***"Not Worth the Risk—Even If It's Legal,"*** consisting of English and Spanish language television and radio spots, a newspaper article (English and Spanish distributions) and two educational brochures, one targeting teens and one targeting parents. All of the campaign elements are posted for viewing on www.talkaboutrx.org.
- ***"Maximizing Your Role as a Teen Influencer: What You Can Do To Help Prevent Teen Prescription Drug Abuse,"***—turn-key educational workshop materials (Power Point presentation with presenter's notes and a comprehensive Presenter's Guide) to equip teen influencers (e.g., parents, teachers, school administrators, coaches, community leaders, physicians and pharmacists) with the knowledge and skills to communicate with teens and help curb prescription drug abuse.
- NCPIE has begun development of a third resource, an online ***"Tool Kit for Curbing Prescription Medicine Abuse on America's College Campuses,"*** in October 2009.

Safety Issues Related to Proper Disposal of Pharmaceuticals—Proper disposal of unused medications has become a visible and sensitive public health and environmental issue. Goals of proper disposal programs include: 1) Prevent environmental exposures and impacts from improper pharmaceutical disposal, especially to the aquatic ecosystem; 2) Minimize accidental overdoses by people, pets and wildlife; 3) Limit opportunities for drug-related crime and subsequent abuse; 4) Provide a safe alternative to drug stockpiling in homes; 5) Preclude outdated drug donations; and 6) Facilitate pharmacoeconomic assessments of waste and prescriptions, insurance, and reimbursement and dispensing policies and practices.

NCPIE distributes a handout for consumers on proper disposal entitled, **"Tips on Safe Storage and Disposal of Your Prescription Medicines." (www.talkaboutrx.org).** NCPIE is also a collaborative partner and participant in

The Safe Medicine Disposal for Maine. NCPIE is represented on the project advisory team for this statewide pilot disposal program developed in Maine with grant support from the U.S. Environmental Protection Agency (EPA). The program provides a safe and anonymous method of drug disposal for Maine residents and is the first of its kind in the country. For additional information see: **http://www.safemeddisposal.com/**.

Safety Issues Related to the Prevention of Medication Errors—NCPIE is a member of the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP), a coalition of over two dozen leading national healthcare organizations who work collaboratively to address the interdisciplinary causes of medication errors and to promote the safe use of medications. The U.S. Pharmacopeia spearheaded the formation of NCC MERP and is a founding member and Secretariat for NCC MERP. The Department of Veterans Affairs is also a member of NCC MERP. Currently, 14 NCC MERP Recommendations reside on the NCC MERP Web site at: **http://www.nccmerp.org/councilRecs.html**. Select sample titles include: *Recommendations to Enhance Accuracy of Prescription Writing; Recommendations for Health Care Organizations to Reduce Medication Errors Associated with the Label, Labeling, and Packaging of Pharmaceutical (Drug) Products and Related Devices; and Reducing Medication Errors Associated with At-risk Behaviors by Healthcare Professionals.*

Safety Issues Related to Safe and Appropriate Use of Acetaminophen Products—NCPIE is currently participating in two coalitions (Maryland Acetaminophen Coalition and the American Pharmacists Multi-Stakeholder Coalition) addressing the safe use of OTC and prescription medicines containing the active ingredient acetaminophen. Acetaminophen is sold under several brand names and is also available in over 600 cough and cold products, sleep aids, and prescription pain relievers.

The wide spread utilization of acetaminophen by patients may increase the incidence and prevalence of misuse, which can lead to severe healthcare outcomes. Many cases of overdose are caused by patients inadvertently taking more than the current recommended dose of a particular product, or by taking more than one product containing acetaminophen (e.g., an over-the-counter product and a prescription drug containing acetaminophen).

Safety Issues Related to Older Adults and Medication Use/Misuse—NCPIE, in 2007, developed and launched **The Medication Use Safety Training for Seniors**™ program **(MUST for Seniors**™). This turn-key, online educational program for older adult medicine users, caregivers, and community-based programs that address older adult health and wellness includes a complete menu of video vignettes, Power Point presentations with accompanying scripts and a range of supporting educational handouts for individuals or group participants. See: www.mustforseniors.org.

The following patient medication safety issues were first described by NCPIE in a forward-looking **October 1987 referenced report, "Priorities and Approaches for Improving Prescription Medicine Use by Older Americans."** The report summarized the problem of improper medication use among older adults, its consequences, and factors contributing to the problem; identified priorities for resolving factors leading to medication misuse; and suggested practical approaches to program developers for taking action in the following key priority areas: 1) Poor Communication Between Older Patients And Health Professionals; 2) Polypharmacy (the use of multiple medicines); 3) Multiple Health Care Providers 4) Altered Drug Action and Response With Advancing Age; 5) Inability To Take The Medication As Prescribed, and 6) Deliberate Nonadherence.

Safety Issues Related to Children and Improper Medicine Use—In 1989 NCPIE produced a referenced report entitled, **"Children and America's Other Drug Problem: Guidelines for Improving Prescription Medicine Use Among Children and Teenagers."** Key findings from the report included the finding that improper medicine use among children is a widespread problem. Adolescents are even more likely not to take medicine as prescribed than children under age 13. Four types of improper medicine misuse commonly occur: 1) Stopping a medicine too soon; 2) Not taking enough of a medicine; 3) Refusing to take a medicine; 4) Taking too much of a medicine. The consequences of such improper medicine use are serious: 1) Dangerous health outcomes; 2) Inadvertent treatment errors; 3) Life-threatening adverse effects; 4) Unpleasant side effects; 5) Unnecessary diagnostic and treatment costs; and 6) Greater risk of accidental poisoning.

Select Best Practices, Programs or Policies that NCPIE Member Organizations Employ to Enhance Medication and Patient Safety

NCPIE is pleased to share best practices, programs, or policies that select member organizations employ to enhance safe and appropriate medicine use and patient safety. The following represents only a partial list of such members' work products:

- American Pharmacists Association
- American Society of Health System Pharmacists
- Academy of Managed Care Pharmacy
- Health Resources and Services Administration, Office of Pharmacy Affairs
- Institute of Safe Medication Use (ISMP)
- Pharmacy Coalition Work Product

American Pharmacists Association (APhA)

—Medication Therapy Management (MTM) Central—APhA Web content; comprehensive information about MTM including links to:

- MTM Certificate Program
- MTM Services Continuing Education Programs
- APhA MTM Digest
- 100 MTM Tips for the Pharmacist

http://www.pharmacist.com/AM/Template.cfm?Section=MTM&Template=/TaggedPage/TaggedPageDisplay.cfm&TPLID=87&ContentID=19154

—"Pharmacist Clinical Services Improve Health Care Quality, Lower Health Care Costs—Potential Medication Therapy Management Impact: $30 Billion in Savings"

Information presented by APhA to demonstrate possible savings if pharmacist clinical services were more widely available for the following diseases: Diabetes, Cardiovascular Disease, and Asthma. Includes the following data from the Department of Veterans Affairs (VA): By extrapolating the average salary data for a pharmacist, the VA expects to see an annual $368,000 in savings from each pharmacist by providing clinical pharmacy services. (Schumock OT, Butler MC, Meek PD, Vermeulen LC, Arondeker BV, Bauman JL. *Evidence of the Economic Benefit of Clinical Pharmacy Services: 1996–2000* Pharmacotherapy 2003; 23(1):113–132)

American Society of Health-System Pharmacists (ASHP)

ASHP supports all pharmacists being able to play a leadership role in medication-use safety. In larger hospitals, a dedicated position is necessary to oversee the management of medication safety initiatives. This new position has emerged to provide leadership in medication-use quality and safety: the Medication Safety Officer (MSO). The MSO is a practitioner who serves as an authoritative leader within the organization on safe medication use. While an MSO can be a nurse or physician, this role is usually filled by a pharmacist or pharmacy manager in the Department of Pharmacy. To become an MSO, requirements include formal training in medication safety and quality best practices. Pharmacists who choose to specialize in medication-use safety undergo 10 years of educational training, including an accredited postdoctoral residency training program. Job responsibilities of an MSO include, but are not limited to, the following:

1. Managing information on patients and medication
2. Overseeing processes for prescribing and monitoring use of medication
3. Optimizing communication methods to minimize risk for errors
4. Minimizing potential for error in medication labeling, packaging, and nomenclature
5. Standardizing administration, dosing, and storage of medication
6. Overseeing preparation, distribution, dispensing, and administration of medication
7. Evaluating and oversee acquisition, use, and monitoring of medication delivery devices
8. Maintaining safe environmental conditions for patients and staff
9. Ensuring healthcare staff competence, education, and proficiency
10. Ensuring patient education
11. Maintaining quality processes and oversee risk management
12. Ensuring legal and regulatory compliance
13. Serving as a liaison to the public for the organization and management
14. Evaluating integration of technology, automation, and clinical information systems
15. Promoting Best Practices for safe medication use
16. Collaborating with other healthcare disciplines and hospital leadership to coordinate system-wide medication safety initiatives.

ASHP compiles its policy positions, statements, guidelines, technical assistance bulletins, therapeutic position statements, therapeutic guidelines, and selected ASHP-endorsed documents in ***ASHP's Best Practices for Hospital & Health-System Pharmacy***. This compilation is updated annually, and provides guidance and direction to ASHP members and pharmacy practitioners and to other audiences who affect pharmacy practice.

Academy of Managed Care Pharmacy (AMCP)

The Framework for Quality Drug Therapy (http://www.fmcpnet.org/index.cfm?p=132D8447)

This uniquely designed self-assessment tool is intended to be used by individual pharmacists and other healthcare practitioners and by organizations of virtually any size, from a physician's office to a large corporate health plan. The interactive tool provides individual practitioners and organizations with an online step-by-step process to identify, evaluate and improve upon specific task, skills and functions that contribute to effective medication therapy management. By answering a series of questions contained in the interactive self-assessment tool, the program helps identify drug therapy management areas ripe for improvement. The program then populates any one of three action plan templates chosen by the user. The action plan template provides a format for defining measurable goals, assigning responsibilities, identifying available resources, and tracking progress, thus beginning a continuous quality improvement process.

Health Resources and Services Administration, Office of Pharmacy Affairs

"Patient Safety and Clinical Pharmacy Services Collaborative Change Package," (PSCS; version 11, August 1, 2008). The *"Patient Safety and Clinical Pharmacy Services Collaborative Change Package,"* is organized into strategies. Each strategy includes change concepts, each of which is accompanied by action items (e.g., "assess organizational needs for quality . . ."). The *Change Package* also denotes links to current corresponding national initiatives, helpful tools and resources, and definitions relevant to the proposed material. The following is one illustrative strategy:

Strategies to Achieve Accountability for Results

IV. Safe Medication Use Systems: Develop and operate by safe medication-use practices

Key Change Concepts for Improved Patient Safety and Clinical Pharmacy Systems

J. Systematically introduce and institutionalize safe medication-use practices and monitoring procedures.

Suggested Action Items *(Range from J1.–J11; Representative sample below).*

J1. Eliminate the practice of providing free samples, or establish a strict set of guidelines for acceptance and monitoring of samples based on a rational formula for the organization.
J2. Require double-checking, especially during the times when pharmacist is unavailable (e.g., develop and utilize policies requiring two nurses to verify the right drug when nurses access medication storage).
J3. Write notes in a standardized way based on locally developed guidelines shared among providers; for example, list "do not use" abbreviations on the medication form

Institute for Safe Medication Practices (ISMP)

ISMP Self-Assessments

The Institute for Safe Medication Practices (ISMP) makes available to healthcare organizations several ISMP Medication Safety Self Assessments®. These tools are designed to help healthcare organizations assess the medication safety practices in their respective institution surrounding the use of medication therapy, identify opportunities for improvement, and compare individual organizational experience with the aggregate experience of demographically similar organizations.

The self-assessments contain items that address the use of medications in the clinical setting, many of which are on the ISMP list of high-alert medications. Many of the items included represent system improvements and safeguards that ISMP has recommended in response to analysis of medication errors reported to the USP–ISMP Medication Errors Reporting Program, problems identified during on-site consultations with healthcare organizations, and guidelines in the medical literature. Available Self Assessments include:

- Acute Care—ISMP Medication Safety Self Assessment® for Hospitals

2004 Self-assessment
2000 Self-assessment
- *Antithrombotic Therapy*
- *Bar Coding Assessment*
- *Community/Ambulatory Pharmacy*
- *Physician Practices*
- ISMP Medication Safety Self Assessment® for Automated Dispensing Cabinets

Pharmacy Coalition Work Product

1. **Principles of a Sound Drug Formulary System**

A coalition of national organizations representing healthcare professionals, government, and business leaders formed a working group (Including the Department of Veterans Affairs. See Appendix III) to develop a set of principles specifying the essential components that contribute to a sound drug formulary system. The Coalition was formed in September 1999 in response to the widespread use of drug formularies in both inpatient and outpatient settings and the lack of understanding about formularies among the public. The passage of Federal legislation providing a prescription drug benefit for Medicare beneficiaries also brought increased attention to the appropriate role and management of drug formulary systems within drug benefit programs. This document contains "Guiding Principles" that the Coalition believes must be present for a drug formulary system to appropriately serve the patients it covers. See: **http://www.amcp.org/amcp.ark?p=AA8CD7EC**

How The NCPIE Coalition Works to Meet its Mission

NCPIE works to meet its mission to "stimulate and improve communication of information on the appropriate use of medicines to consumers and healthcare professionals," through both in-house development and implementation of educational products or programs and through convening or participating in collaborative programs with both member and non-member organizations. Examples of both approaches include:

Dedicated/Recurring Event of Observance

- In October 1986, NCPIE conducted its first annual **"Talk About Prescriptions" Month**. The purpose of **"Talk About Prescriptions" Month** (TAP Month) is to help ensure that safe and appropriate medicine use through high-quality medicine communication is positioned as an important public health issue. TAP Month also provides NCPIE a regularly-scheduled platform for announcing new educational products, programs or services to promote its organizational mission. The theme for NCPIE's upcoming, 24th annual TAP Month, October 2009 is, **Talk About Prescriptions: *"Communication is Key."***

Establish Key Partnerships

- In-house development, January 2002 launch, and ongoing implementation of **"Be MedWise" to Promote Safe Use of Over-the-Counter Medicines (www.bemedwise.org)**. NCPIE conceptualized this ongoing, Web-based public education campaign and invited the Food and Drug Administration and the American Pharmacists Association to participate in its launch at a national Press Club media briefing. Dr. Richard Carmona, M.D., MPH, FACS, U.S. Surgeon General, participated in a subsequent media briefing in September 2003 to expand the scope of the campaign. NCPIE also licenses content from the campaign to support two statewide collaborative programs, **"Be MedWise" Tennessee, and "Be MedWise" Arkansas.** Lead State organizations are the Universities of Tennessee and Arkansas' Cooperative Extension Services, the University of TN College of Pharmacy and the Univ. of Arkansas College of Pharmacy.

Convene Expert Project Advisory Team

- Formulation of an external Project Advisory Team (PAT) to assist in the development, promotion, and dissemination of a turn-key educational workshop kit, **"Maximizing Your Role as a Teen Influencer: *What You Can Do To Help Prevent Teen Prescription Drug Abuse.*"**. The PAT for this project, which will launch in October 2009 in conjunction with NCPIE's annual "Talk About Prescriptions" Month campaign includes representatives from 14 organizations.

  NCPIE also convened an external Project Advisory Team for the development, promotion, and 2007 launch of its ongoing online NCPIE program, **"Medication Use Safety Training for Seniors™ (MUST for Seniors™)."**

Participate in External Coalitions

- NCPIE currently participates in the following external coalitions or special projects:
  - National Coordinating Council for Medication Reporting and Prevention (NCC MERP)
  - National Consumers League/Agency for Health Care Research and Quality National Medication Adherence Public Awareness Campaign
  - Safe Medication Disposal for ME (Maine) Program—Member of project advisory team
  - "*Follow Directions: How to Use Methadone Safely"* Campaign Partner
  - New England Health Care Institute (NEHI) medication adherence improvement project
  - Maryland State Board of Pharmacy Acetaminophen Safety Campaign
  - American Pharmacists Association Safe Use of Acetaminophen Products Coalition

Use the Internet and (Pending) Use of Social Media

- NCPIE currently maintains or promotes four educational Web sites:

  www.talkaboutrx.org—primary site; home for "Talk About Prescriptions" Month;
  www.bemedwise.org—safe use of over-the-counter (OTC) medicines;
  www.mustforseniors.org—targeting older adults and caregivers;
  www.learnaboutrxsafety.org—targeting families, including older adults, caregivers, parents and children; developed collaboratively for The Center for Improving Medication Management (SureScripts) who own/maintain the site.
- Upcoming campaign (online Tool Kit to address medicine abuse on college campuses) will include outreach via social media, including Facebook and Twitter).

I would once again like to thank you for inviting me to testify before this Subcommittee. I appreciate the work of this Subcommittee on Oversight and Investigations of the House Committee on Veterans' Affairs. On behalf of all NCPIE member organizations I thank you for your trust in our ability to assist you with this important work. I look forward to answering any questions you might have.

Prepared Statement of Solomon Iyasu, M.D., MPH, Director, Division of Epidemiology, Office of Surveillance and Epidemiology, Center for Drug Evaluation and Research, Food and Drug Administration, U.S. Department of Health and Human Services

INTRODUCTION

Mr. Chairman and Members of the Committee, I am Dr. Solomon Iyasu, Director, Division of Epidemiology, within the Office of Surveillance and Epidemiology in the Center for Drug Evaluation and Research (CDER) at the Food and Drug Administration (FDA or the Agency), which is part of the Department of Health and Human Services (HHS). I am pleased to be here today to discuss FDA's role in identifying and communicating drug safety issues, as well as our collaboration with the Department of Veterans Affairs (VA). We will first discuss the importance of FDA drug regulation, including how the Agency manages drug safety issues and informs the public when drug safety concerns arise. We will also discuss some specific examples of how FDA and the VA have collaborated in furthering our mission to protect the public health and keep our drug supply safe.

FDA DRUG REGULATION

FDA promotes public health through the regulation of prescription and over-the-counter drugs, which are an increasingly critical component in improving the health of many Americans. FDA is charged by Congress with the authority to review new drug applications for safety and effectiveness. FDA's drug review process is recognized worldwide as the gold standard, and we actively monitor the scientific bases for our processes to ensure that they reflect advances in medical science.

Approval of a drug product is based on FDA's acceptance and review of data collected during the course of the drug's development, including the results of clinical trials, demonstrating that the drug is safe and effective for its intended use. At least half of the effort by FDA's premarket reviewers is dedicated to the assessment of safety. Major changes have taken place in how drugs are evaluated, including a complete evaluation of their metabolism, their interactions with other drugs, and po-

tential differences of effectiveness or safety in people of different genders, ages, and races. In addition, FDA staff perform systematic assessments of safety that yield comprehensive reviews, focusing on the potential problems with the greatest clinical importance. Adverse reactions reported during the clinical trials of the drug are included in the labeling information, even if they occurred in a small number of individuals, so that health professionals are aware of the scope of the potential reactions and can advise their patients accordingly.

All drug products contain risks as well as benefits, and it is often impossible to predict which individuals may have increased sensitivity to particular drugs. Before approving a drug, FDA takes into account the known risks associated with the drug, along with the benefits the drug will provide. FDA's responsibilities for oversight of the entire life cycle of drugs—from premarket drug testing and development through drug approval, postmarket surveillance, and risk management—have never been more important. No amount of premarket study can provide all of the information about effectiveness or all the risks of a new drug when it is used by the general population in the myriad ways not studied during clinical trials. As a result, FDA's postmarket drug safety program plays an essential role by collecting and assessing information about adverse events and medication errors identified after approval. A key role of our postmarket safety system is to detect serious unexpected adverse events and take definitive action when needed.

Health professionals may observe differences from clinical trial results in both the incidence and/or types of adverse drug experiences. FDA is committed to improving the ability of healthcare professionals to predict which patients might experience adverse events with a given drug. FDA continuously seeks to provide the means for translating new scientific advances into benefits for patients (for example, biomarkers and pharmacogenomics) to take advantage of new ways to monitor the performance of marketed drugs, and to communicate this information to healthcare professionals and patients to help ensure the safe use of drugs.

Another critical aspect to drug regulation is the safety of products imported into the United States. On July 1, 2008, FDA issued the "Import Safety–Action Plan Update." The update outlines the significant progress FDA has made and the key steps that are planned for the future to enhance the safety of imported goods. FDA has taken strong enforcement actions, signed agreements with key trading partners, hosted bilateral and multilateral discussions, shared critical information on safety and best practices, and begun a process to improve safety practices, both inside and outside of government. FDA has increased its presence abroad by establishing offices in China, India, Europe, and Latin America at present. FDA is seeking to ensure that imported drug products are safe and effective prior to reaching U.S. ports of entry. Among other things, FDA is pursuing this goal by maximizing foreign product preapproval inspections, increasing FDA inspections, increasing the sharing and use of foreign competent authority inspection reports and other information, developing plans to use third-party certification, and providing technical assistance to countries that have less developed regulatory systems to ensure product safety.

Below we will discuss how FDA manages drug safety issues in general, and we will highlight initiatives in place to further enhance FDA's postmarket drug safety monitoring program.

HOW FDA MANAGES DRUG SAFETY ISSUES

Once FDA approves a drug, the postmarket monitoring stage begins. A drug manufacturer is required to submit regular postmarketing reports to FDA on its drug. These reports include critical information about adverse events associated with the use of one or more drugs. Reports are submitted in an expedited fashion for serious and unexpected adverse events, and periodically for other adverse events. Manufacturers submit several other types of postmarketing reports, including new clinical trial results. Also during this period, we continuously receive adverse event reports directly from the public, such as healthcare professionals and patients through our MedWatch program. Stored in a computerized database, these reports are reviewed and analyzed by FDA epidemiologists and safety evaluators to assess the frequency and seriousness of the adverse events and to determine their association, if any, with medication usage. An adverse event may occur because of simple or complex reasons, including drug exposure, an interaction between one or more drugs, other therapies, environmental factors, an individual's characteristics, and underlying diseases. Our response to information from this ongoing surveillance depends on an evaluation of the aggregate public health benefits of the product compared to its evolving risk profile.

Decisions about regulatory action in response to evidence of a drug safety risk are complex, taking into account many factors. The actions taken depend on the characteristics of the adverse events, the frequency of the reports, the seriousness of the

diseases or conditions for which the drug provides a benefit, the availability of alternative therapies, and the consequences of not treating the disease. As more becomes known about the potential risks or benefits of a drug, often its FDA-approved labeling will be revised so that it better reflects information on appropriate use. If labeling alone is inadequate to manage risks, additional actions may include revising drug names or packaging, issuing "Dear Health Care Professional" letters (sometimes referred to as "Dear Doctor" letters), disseminating educational/special risk communications, requiring restricted distribution programs, or withdrawing a drug's approval.

HOW FDA COMMUNICATES ABOUT DRUG SAFETY ISSUES

FDA uses a broad range of methods to communicate drug safety information to the public. Certain forms of communication are targeted to specific audiences (e.g., healthcare professionals or patients). Others are directed at more than one group to ensure widespread dissemination of information about important drug safety issues, including emerging drug safety issues. FDA continuously evaluates its communication efforts and modifies them to enhance their accessibility and effectiveness. We welcome public comment at any time, suggesting ways to improve our safety communications. The different types of drug safety communications are described in more detail below.

Labeling. FDA-approved drug product labeling is the primary source of information about a drug's safety and effectiveness, and it summarizes the essential scientific information needed for the safe and effective use of the drug. Labeling for prescription drug products is directed to healthcare professionals but may include patient counseling information as well. For some prescription drugs, such as oral contraceptives and estrogens, FDA determined several years ago that the safe and effective use of these drugs required that additional labeling in nontechnical language be distributed directly to patients by their healthcare professional or pharmacist (Title 21 of the *Code of Federal Regulations* (CFR) 310.501 and 310.515). In addition, FDA may require Medication Guides, a type of patient-directed labeling, for products it determines pose a serious and significant public health concern (21 CFR 208) as part of a risk evaluation and mitigation strategy (REMS). FDA-approved patient labeling also may be provided by manufacturers for other drugs.

Early Communications about Ongoing Safety Reviews. Since August 2007, FDA has issued Early Communications about Ongoing Safety Reviews to keep healthcare professionals and the general public informed of postmarket safety issues that are currently being evaluated by FDA. Early Communications are issued at the beginning of FDA's assessment, prior to conclusive determination of the clinical or public health significance of the information under evaluation, and before a decision has been made about what regulatory actions, if any, should be taken. They reflect FDA's current analysis of available data concerning these drugs; posting the information as an Early Communication does not mean that FDA has concluded there is a causal relationship between the drug and the emerging safety issue. It also does not mean that FDA is advising healthcare professionals to discontinue prescribing these products. In general, Early Communications have included a time frame for when FDA anticipates completing the safety review and providing followup.

Public Health Advisories (PHAs). FDA issues PHAs to provide information regarding important public health issues to the general public, including patients and healthcare professionals. For example, PHAs may highlight important safety information, inform the public about the completion of FDA's evaluation of an emerging drug safety issue, announce the implementation of methods to manage the risks identified for a marketed drug, or provide other important public health information.

PHAs regularly include recommendations to mitigate a potential risk and often are issued in conjunction with other drug safety communications, such as Health Care Professional Sheets. PHAs related to drugs are available through CDER's Web site and disseminated via the MedWatch Partners Program.

Health Care Professional Sheets. FDA issues Health Care Professional Sheets, which provide a summary of important and often emerging drug safety information for a particular drug or drug class. Health Care Professional Sheets begin with a summary "Alert" paragraph, followed by more detailed sections explaining the Alert, including clinical considerations or recommendations for the healthcare professional, information that patients should be made aware of and discuss with their healthcare professional, a summary of the data that were the basis for the recommendations, and, when applicable, implications of the Alert. Health Care Professional Sheets are intended to provide adequate factual information to address potential questions from patients and facilitate a healthcare professional's consideration of the drug safety issue.

Other Methods of Communication. FDA continues to explore other methods of making its written communications more effective, as well as the use of other media such as podcasts, video broadcasts and conference calls, to disseminate drug safety information.

Manufacturers also use various methods to communicate drug safety information. For example, a sponsor may distribute a "Dear Health Care Professional" letter to convey important information regarding a marketed drug. "Dear Health Care Professional" letters may be used to disseminate information regarding a significant hazard to health, announce important changes in product labeling, or emphasize corrections to prescription drug advertising or labeling.

INITIATIVES TO IMPROVE DRUG SAFETY

Drug Safety Oversight Board

The Drug Safety Oversight Board (DSB or the Board) was established in 2005 to oversee the management of drug safety issues and communication to the public about the risks and benefits of medicines. The Board's responsibilities include conducting timely and comprehensive evaluations of emerging drug safety issues for healthcare professionals and patients, and ensuring that experts both inside and outside of FDA give their perspectives to the Agency. The DSB also makes recommendations regarding disputes over scientific data and implements drug safety policies. In addition to making FDA's decisions on drug safety more transparent, the Board is a means to assure the public and medical profession that guidance has not been unduly influenced by the pharmaceutical industry.

The DSB oversees drug safety issues within FDA's CDER, and is made up of FDA and medical experts from other government health agencies and government departments, including the VA. Along with other FDA colleagues, I am a primary participant from the Office of Surveillance and Epidemiology (OSE), in addition to the OSE Director and my counterpart in OSE's Division of Pharmacovigilance. In addition to the VA, other Federal agency Board members include representatives from the National Institutes of Health, the Centers for Disease Control and Prevention, the Agency for Health Care Research and Quality, and the Department of Defense.

As a result of its partnership with FDA on the DSB, the VA shared the results of its own analysis involving the pain reliever propoxyphene with FDA. Based on these data as well as other data, in July 2009, FDA took action to require manufacturers of propoxyphene-containing products to strengthen the label emphasizing the potential for overdose when using these products, and to provide a medication guide to patients stressing the importance of using the drugs as directed. Among other things FDA is doing to further assess the safety of this product, the Agency is working with the VA to explore whether we can study how often the elderly are prescribed propoxyphene instead of other pain relievers and the difference in the safety profiles of propoxyphene compared to other drugs.

Other FDA/VA Collaborations

Collaborations between the VA and CDER's Office of Surveillance and Epidemiology, as well as with other FDA Centers, enhance our understanding of postmarket safety issues occurring in FDA-regulated products.

In January 2007, and again in 2008, FDA and the VA signed a Memorandum of Understanding (MOU) for sharing information to enhance postmarket surveillance efforts and other drug and vaccine safety projects. The goals of the collaboration are to explore ways to promote efficient use of tools and expertise for product risk identification, validation, and analysis and to build infrastructure and processes that meet shared needs for evaluating the safety, efficacy, and use of drugs, biologics, and medical devices.

Also, in August 2008, FDA and the VA signed an InterAgency Agreement (IAA), which allowed FDA to provide funding to the VA for work on safety issues of mutual interest. The IAA allowed funding for personnel time and programming costs associated with analysis of VA data to explore questions of interest that were raised by FDA, but also of interest to VA. This agreement is currently in the process of being renewed for another year.

In addition, CBER and the VA continue collaboration on the Vaccine Safety Adverse Event Tracking and Safety Pilot Project. The focus of this initiative is the influenza immunization pilot study in the Central Veterans Health Administration (VHA) Database which will track adverse events after administration of influenza vaccine in a cohort of approximately 1 million VHA patients. It is anticipated that an additional 900,000 more persons will be added to the Central Database (bringing the total number of persons in the cohort to 2 million) in October 2009.

Also, the VA and FDA's CDRH are working together to better understand adverse events related to cardiac catheterization procedures. The VA has developed a

workflow system that allows for the integration of adverse event data reporting for review and discussion at a later date. This information is then shared with CDRH at regular intervals. The VA and CDRH are developing ways to share information in a similar fashion for endoscopes.

Food and Drug Administration Amendments Act of 2007 (FDAAA)

As you know, in September 2007, Congress passed FDAAA, which included new resources for medical product safety and new regulatory tools and authorities to ensure the safe and appropriate use of drugs. For example, under FDAAA, FDA can require drug sponsors to make certain safety-related labeling changes and conduct postmarketing studies and clinical trials instead of relying on voluntary actions. In addition, if FDA determines that a REMS—risk evaluation and mitigation strategy—is necessary to ensure that the benefits of a drug outweigh the risks of the drug, FDA can require manufacturers to submit a REMS when a drug comes on the market, or later if FDA becomes aware of new safety information.

Sentinel Initiative

FDAAA requires the HHS Secretary to develop methods to obtain access to disparate data sources and to establish a postmarket risk identification and analysis system to link and analyze healthcare data from multiple sources. The Sentinel Initiative is FDA's response to this mandate. Its goal is to build and implement a new active surveillance system that will eventually use electronic health information to monitor the safety of all FDA-regulated products. On May 22, 2008, FDA launched the Sentinel Initiative with the ultimate goal of creating and implanting the Sentinel System—a national, integrated, electronic system for monitoring medical product safety. The Sentinel Initiative is a long-term effort that must proceed in stages, and this effort is well under way. FDA is collaborating with the Federal and private sector in various activities that will inform the development of this system.

In December 2008, FDA held a public meeting on the Sentinel Initiative to obtain input from stakeholders about the structure, function, and scope of the project. The Director for the Center of Medication Safety at the VA was among the participants at this day-long meeting, presenting on the issue of risk communication.

As an initial step to creating the Sentinel System, FDA is initiating various pilot efforts to further the science of medical product surveillance. One of these pilots, known as Mini-Sentinel II, will include our Federal partners. We look forward to the VA's participation in this effort. The effort involves creating a distributed system that will focus on developing methodologies to obtain more information on emerging drug safety issues. Mini-Sentinel II is a small-scale effort to conduct the types of safety evaluations that FDA envisions doing on a larger scale with the Sentinel System. Medical product-adverse event pairs will be selected based on identification of priority safety issues from FDA's medical product Centers. Then a protocol for a query will be developed and agreed to by participating Federal partners. Subsequently, each participating Federal partner will perform the analysis in their database. The query will be translated into analytical code by the partner specifically developed and suited for the partner's database structure. Summary results of each Federal partner's analysis will be submitted to FDA for further consideration. Lessons learned from this pilot will inform the development of the Sentinel System.

The Sentinel System will augment the Agency's current postmarketing surveillance tools and strengthen FDA's ability to ensure that safe and effective new drugs are available to the public and that the risks of marketed drugs are well understood.

CONCLUSION

FDA has a critical role in the detection and management of safety issues that are identified after a drug is approved, including a critical role in communicating information to the public. Our goal, regardless of the communication tool employed, is to make the most up-to-date drug safety information available to the public in a timely manner so that healthcare professionals and patients can consider the information when making decisions about medical treatment and be aware of uncertainties in the data. Our ability to fulfill our mission is enhanced by our partnerships with patients, physicians, pharmacists, industry, State regulators, and other Federal partners like the VA. Together we can help ensure the safe use of marketed drugs by providing the best possible information to the American public.

Once again, thank you for the opportunity to testify before the Committee today. We are happy to respond to questions.

Prepared Statement of Belinda J. Finn, Assistant Inspector General for Audits and Evaluations, Office of Inspector General, U.S. Department of Veterans Affairs

INTRODUCTION

Mr. Chairman and Members of the Subcommittee, thank you for the opportunity to discuss systemic weaknesses impacting the Veterans Health Administration's (VHA) ability to accurately account for its inventories of non-controlled drugs in VHA medical facilities and consolidated mail outpatient pharmacies (CMOPs). We issued two recent Office of Inspector General (OIG) reports, *Audit of VA Consolidated Mail Outpatient Pharmacy Inventory Accountability* and *Audit of Veterans Health Administration's Management of Non-Controlled Drugs,* related to this issue. I am accompanied by Irene Barnett, Ph.D., Audit Manager, Bedford Office for Audits and Evaluations, OIG.

BACKGROUND

VHA medical facilities and CMOPs dispensed about 126 million prescriptions for VA patients and spent $3.7 billion on pharmaceuticals in fiscal year (FY) 2008. Prescription drugs are generally categorized as controlled or non-controlled. Non-controlled drugs are not regulated under the Controlled Substances Act 1970 due to the reduced risk for abuse and addiction. Approximately 95 percent of the pharmaceutical spending was on non-controlled drugs. Also, non-controlled drugs are not subject to the same stringent inventory and oversight controls that controlled drugs are subject to, yet some non-controlled drugs are expensive, others contain active ingredients that can be used to manufacture illicit drugs, and some are considered to be at high risk of diversion given the high street value of the specific drug. Within VHA, prescription medications are generally dispensed directly to veterans by facility inpatient or outpatient pharmacies or by mail from a medical facility's pharmacy or a CMOP. The CMOPs spend about twice as much money on pharmaceuticals than VHA medical facilities. As part of our recent oversight of pharmaceutical inventories, we visited two of VHA's seven CMOP operations in Charleston, SC, and Dallas, TX, and six of VHA's medical facilities in Fayetteville, NC, New York, NY, Long Beach, CA, Wichita, KS, Seattle, WA, and Spokane, WA. In addition, we also analyzed the inventory records of over 30 VA medical centers.

We reported VHA medical facilities and CMOPs could not accurately account for non-controlled drug inventories because of inadequate inventory management practices, recordkeeping, and inaccurate pharmacy data. VHA needs to improve its ability to account for non-controlled drugs to reduce the risk of diversion and standardize its pharmacy inventory practices among its medical facilities and CMOPs. Without improved controls, VHA cannot ensure its non-controlled drug inventories are appropriately safeguarded, nor can VHA accurately account for these expensive inventories.

FINDINGS

VHA cannot accurately account for its non-controlled drug inventories because it has neither implemented nor enforced sufficient controls to ensure pharmacy inventory practices are standardized and pharmacy data is accurate. Furthermore, VHA does not currently require its facilities to monitor any non-controlled drugs on an ongoing basis.

We found that both CMOPs and VHA medical facilities maintain inventory management controls and use systems of inventory control that rely upon annual physical counts of drugs. However, we identified significant weaknesses in how well the facilities perform physical counts and adjust inventory records.

Inadequate Inventory Controls Led to Significant Inventory Variances

VHA Handbook 1761.2, *VHA Inventory Management*, requires that an annual wall-to-wall physical inventory be performed for all items. In addition, *VHA's Pharmacy Inventory Guidelines* state that inventory quantities of an open product should be estimated to the nearest tenth of a bottle. The CMOPs did not perform complete annual physical counts for all items, as required and inconsistently estimated their inventory quantities of open products. Additionally, the inventory management system used by most CMOPs does not always track drug dispensing. CMOP personnel physically count all drugs that are manually dispensed, but they do not count all drugs dispensed from individual pill dispensers because they considered the physical count of open products to be too labor intensive.

We performed inventory analyses at two of VA's seven CMOPs supporting operations nationwide and identified pill variances ranging from a negative variance of 3,092 pills to a positive variance 192,498 pills. The existence of these variances demonstrated the unreliability and inaccuracy of the CMOPs' inventory records. Fur-

ther, 14 of 18 pharmaceutical items that we reviewed had positive variances. These variances can enable and mask a deliberate diversion and loss of drugs. CMOP personnel were unable to explain the positive or negative pill variances between the actual pill counts and the amounts we computed as the ending inventory. However, they indicated the variances might be the result of the inventory management system inaccurately tracking dispensed pills and because annual wall-to-wall physical inventories were not completed for all drugs.

Physical inventories performed within VA medical facilities did not provide adequate accountability for non-controlled drugs. VHA requires pharmacy managers to verify that physical inventories are conducted completely and accurately by conducting random checks of at least 25 items. None of the pharmacy managers at the six VHA medical facilities we visited were able to demonstrate compliance with this requirement. In fact, we also found that three VHA facilities had not conducted annual physical inventories in 2007 and one did not complete the annual physical inventory in 2008 by the deadline.

VHA pharmacy managers at 9 of the 31 facilities reported that pharmacy personnel are not consistently entering information on quantities of drugs transferred to secondary locations, such as an emergency room or inpatient ward, into the Veterans Health Information System and Technology Architecture (VistA). This results in incomplete information and may explain the negative inventory discrepancies we calculated for selected drug items at many facilities. Dispensing data on non-controlled drug inventories will be understated at facilities where pharmacy personnel are not consistently and accurately entering information on drug transfers in VistA.

We were particularly concerned about negative inventory discrepancies we identified for at least one drug of the five selected for testing at all 31 VHA medical facilities. Negative inventory discrepancies reflect an ending inventory that was lower than it should have been given the quantities of drugs purchased and dispensed by the facility. We estimated that the 31 medical facilities were unable to account for about 380,000 pills, or 8 percent of their total available inventory. We considered the inventory variances to be significant.

Physical inventories act as a check on the effectiveness of other inventory controls. While VHA requires its facilities to conduct annual physical inventories of non-controlled drugs, it does not ensure inventory data is accurate or use the data as a tool to identify drug loss or possible drug diversion. We identified multiple weaknesses in VHA's annual physical inventories of non-controlled drugs. For example, VHA does not require facilities to maintain their annual physical inventory reports for a certain time or record inventory results in a standardized electronic format that could enable a centralized analysis of inventory information. According to VHA officials, the current VistA system cannot provide information to account for a facility's inventory accurately because it lacks the capability to maintain a perpetual inventory.

Other inventory management practices were also reducing the integrity of available inventory management information. For example, CMOPs did not have a policy for controlling and monitoring adjustments to drug inventory records. When CMOPs conduct a physical count for a particular drug and a variance exists between the physical count and the system balance, CMOP personnel simply adjust the inventory system balance so that the inventory balances correspond to actual physical counts. Individuals can make an unlimited number of adjustments in any quantities. Further, CMOP management was not verifying adjustments made to drug inventory balances.

CMOPs did not adequately secure, track, and monitor non-controlled drugs being held for return credit or consistently comply with existing VHA policies. We identified instances where CMOP staff did not maintain a record of non-controlled drugs held for return, or reconcile credits received to the list of non-controlled drugs returned. VHA Directive 2008–021, *Monitoring of Non-Controlled Substance Medication Returns*, requires non-controlled drugs held for return credit to be secured, tracked, and monitored to reduce the possibility of fraud and maximize revenues received through drug returns.

We found that physical security controls were in place to prevent the unauthorized physical removal of pharmaceuticals at the two CMOPs we visited. However, we identified security weaknesses in CMOP inventory information systems. For example, we identified 61 users at the two CMOPs we visited whose inventory management system access allowed them to order, receive, and adjust non-controlled drug inventories. Inventory management system controls were not effectively tracking system user activity to determine if an employee had used all three permissions that allowed users to order, receive, and adjust against the same drug.

Further, CMOP inventory information systems were also at increased risk of inappropriate alterations because generic user accounts enabled employees to order a

drug through the ordering system without being identified as a specific user. The same employee could then use their unique ID and password to reduce the inventory balance and divert the drug.

Drug Transactions Not Accurately and Consistently Recorded

VHA has established some procedures regarding the use of VistA to record drug transactions; however, controls are not in place to ensure that accurate and complete information on drug transactions is captured. For example, we found that local pharmacy personnel are not consistently recording information in VistA on transactions such as pharmacy stock transfers and drug returns. Prescription labels can be reprinted when an original label is damaged although the reprint function in VistA should not generally be used to dispense drugs. Some dispensing data may be incomplete because pharmacy personnel are inappropriately using the label reprint function in VistA to dispense drugs. These practices negatively impacted the reliability of inventory information.

Pharmacy personnel from six medical facilities we visited are using the reprint function to dispense drugs to patients, which can affect the accuracy of drug dispensing captured in VistA. The VistA application lacks adequate controls to track why a reprint label is being generated or to ensure that the function is being appropriately used. Further, VistA captures the quantity of drugs dispensed using the reprint function only if the original prescription was not released to the patient. Without procedures to standardize the use of the reprint function and to capture data on drug transfers, accountability of drug inventories is compromised.

VHA facilities are not consistently capturing information on the quantities of drugs originally dispensed and then returned to inventory for reuse. Pharmacy managers at VHA facilities told us some personnel are returning drugs to inventory without adjusting inventory records in VistA, which inflates a facility's dispensing data. We calculated a positive inventory discrepancy for at least one drug at 24 of 31 VHA medical facilities where we specifically analyzed inventory information. We estimated that these facilities had an excess of about 87,000 pills—or 10 percent—available to dispense. These pills are available to dispense or divert since they do not exist according to the inventory records.

The VHA Directive 98–020, *Drug Accountability Software*, which required facilities to monitor at least 20 non-controlled drugs for possible diversion, expired in 2003. At the time of our audits, VHA had not provided facilities with technical guidance on how to monitor non-controlled drugs on an ongoing basis to detect diversion, or taken steps to improve the usefulness of its annual physical inventory information.

Most pharmacy managers in VHA medical facilities reported that they monitor at least one non-controlled drug for diversion on an ongoing basis, with most monitoring one to five drugs. Typical action includes comparing data on drug purchasing and dispensing to identify unaccounted for drugs. The willingness to monitor certain non-controlled drugs in the absence of VHA policy is a positive action. However, over one-third of pharmacy managers reported that they lack adequate information to monitor non-controlled drugs for diversion. Given the number of high-risk non-controlled drugs medical facilities maintain in stock, VHA needs to identify certain high-risk drugs that should be monitored and provide facilities with guidance on how to monitor and safeguard these drugs on an ongoing basis.

Overall, both VHA's VistA and CMOP inventory management software require improvements to allow medical facilities and CMOPs to better account for pharmacy inventory. In 2003, VHA initiated the Pharmacy Re-engineering project to make improvements to VistA. The project was slated for completion in 2005, but this project has experienced significant delays. Current schedule projections are that the project may not be completed until 2014. Since needed upgrades may take years to be fully implemented, it is vital that VHA take more immediate action to improve accountability over non-controlled drug inventories.

CONCLUSION

With pharmaceutical expenditures exceeding $3.7 billion in FY 2008 and future costs expected to increase, VHA needs accurate inventories and strong record-keeping to account for non-controlled drug inventories. OIG audits reported large variances in the amount of non-controlled drugs at VHA medical facilities and CMOPs and concluded that VHA does not have reliable inventory information that could detect the loss or unauthorized diversion of drugs. The implementation and enforcement of inventory controls to provide accurate and complete information is imperative to VHA's ability to account for, manage, and safeguard non-controlled drugs.

We recommended the Under Secretary for Health take actions to improve accountability over non-controlled drugs, including:

- Enforcing requirements for conducting annual wall-to wall inventories.
- Ensuring annual physical inventory reports are reasonably accurate and pharmacy managers are held accountable for the accuracy of annual inventories.
- Developing policy and establishing controls to monitor and control adjustments to drug inventory records.
- Enforcing compliance with the policy for returned drugs.
- Establishing procedures that restrict a single user from ordering, receiving, and adjusting against the same drug and removing generic user IDs and passwords.
- Developing procedures to identify high-risk non-controlled drugs and requiring pharmacy managers to monitor those drugs.
- Developing appropriate internal controls to ensure information on drug dispensing, drug transfers, and drug returns is accurately and consistently recorded in VistA.
- Limiting access to the VistA label reprint function to appropriate pharmacy personnel.

The Under Secretary for Health agreed with our findings and recommendations to improve accountability over non-controlled drug inventories. VHA provided acceptable implementation plans to address the recommendations. We will followup on the implementation of actions to address the report recommendations.

Mr. Chairman, thank you for the opportunity to discuss these important issues. We would be pleased to answer any questions that you or other Members of the Subcommittee may have.

Prepared Statement of Michael A. Valentino, R.Ph., MHSA, Chief Consultant, Pharmacy Benefits Management Services, Veterans Health Administration, U.S. Department of Veterans Affairs

Mr. Chairman, Ranking Member, and Members of the Committee: thank you for providing me this opportunity to discuss the Department of Veterans Affairs' (VA) Pharmacy Benefits Management Services (PBM) program, including our national Formulary and patient safety initiatives. I am accompanied today by Dr. Chester B. Good, Chair of the VA Medical Advisory Panel and Dr. Paul Tibbits, Deputy Chief Information Officer for Enterprise Development.

Drug therapy is an essential component to quality preventative, curative, and post-operative healthcare. Each Veteran enrolled in the VA healthcare system is eligible to receive prescription medications, over-the-counter medications, and medical and surgical supplies under VA's comprehensive medical benefits package. Generally, these pharmaceuticals must be prescribed by a VA provider and are made available via the VA National Formulary process. In 2008, VA provided approximately 126 million outpatient prescriptions to more than 4.4 million patients. Our error rate for these prescriptions is very low; less than 1 in every 294,000. I can confidently say that VA is meeting the pharmaceutical needs of Veterans and that we are striving every day to provide even better care to more of America's heroes. My testimony will describe how VA manages pharmacy benefits, the offices and procedures we have in place to ensure Veterans receive safe and quality care, and discuss VA's National Formulary. Before concluding, my statement will also provide information on VA's recently initiated Medication Reconciliation program.

Pharmacy Benefits Management

VA's Pharmacy Benefits Management (PBM) program works to enhance the clinical outcomes and improve the health of Veterans through the appropriate use of pharmaceuticals. PBM provides leadership and governance for pharmaceutical activities and professional pharmacy practice in the Veterans Health Administration (VHA) and provides advice and support regarding pharmaceutical issues to Veterans, the Under Secretary for Health, field directors, and pharmacy staff across the system. The PBM organization consists of six primary specialty areas: the Clinical Informatics section; the Consolidated Mail Outpatient Pharmacy (CMOP) program; Adverse Drug Event Reporting (VA ADERS); Emergency Pharmacy Services (EPS); VA National Formulary (VANF) management; and the VA Center for Medication Safety (VA MedSAFE).

Clinical Informatics

The PBM Clinical Informatics section provides operational oversight to the information systems used by PBM and all pharmacy operations nationwide. This section plans and establishes the mechanisms by which VA meets general program goals

for developing and maintaining a nationwide pharmacy information system—the Pharmacy Re-Engineering (PRE) project. The VA PRE project being executed by the VA Office of Information and Technology will provide a system to enhance patient safety and encourage the appropriate use of pharmaceuticals by providing streamlined decision-making information to clinical staff in an integrated fashion.

PRE will provide a flexible technical environment to adjust to and standardize future business conditions while meeting the dynamic needs of the clinical environment. This system will improve major functionalities, including medication order checks, and will provide prescribers with access to pharmacy knowledge systems that can reduce the potential for adverse drug events, improve efficiency by streamlining order processing and dispensing, reduce inventory costs and improve inventory accountability by providing automated tools to track inventory, and improve patient outcomes through medication utilization reporting and monitoring. Our focus, as always, is on the Veteran, and this PBM program provides robust decision support and patient safety features.

An example of how PRE will be used to improve operations is demonstrated by the finding of the Department of Veterans Affairs Office of the Inspector General (OIG) report 08–01322–114 dated June 23, 2009, that reviewed VHA's management of non-controlled drugs. The report states that, "VHA cannot accurately account for its non-controlled drug inventories because it lacks effective controls and reliable information to do so." PRE would assist VA in providing more effective controls. Until automated inventory management tools are made available through PRE, PBM is addressing the OIG findings by educating field staff and developing guidance specific to OIG's recommendations. These interim measures include conducting training on existing requirements, implementing tracking requirements for a sample of high cost/high risk drugs as recommended by OIG, and establishing triggers that warrant focused reviews.

Consolidated Mail Outpatient Pharmacy

There are seven VA CMOP facilities in the National VA CMOP system. These facilities are located in Charleston, SC; Dallas, TX; Hines, IL; Leavenworth, KS; Murfreesboro, TN; Chelmsford, MA; and Tucson, AZ. Together, they interactively provide pharmaceutical support services to VA healthcare facilities located within defined respective CMOP service areas throughout the United States. These service areas include the 21 Veterans Integrated Service Networks (VISN's) in the VA healthcare system, the Civilian Health and Medical Program for the Department of Veterans Affairs (CHAMPVA), and the Department of Defense's (DoD's) Naval Medical Center in San Diego, CA. CMOPs support VA's healthcare mission through advanced automated production technologies to dispense and mail prescriptions to eligible Veterans. This ensures each Veteran receives his or her prescriptions in the most timely, accurate and cost effective manner as possible. Three of five CMOP performance metrics currently exceed six sigma performance.

VA's OIG Report 09–00026–143, dated June 10, 2009, reviewed CMOP contract management. The report found that, "... the National CMOP Office generally complied with Federal and VA acquisition requirements when developing, competing, and monitoring contracts ..." In addition, the OIG auditors "... found no evidence of contract overpayments through (their) review of contract charges where documentation was available ..." However, opportunities for improvement exist in a number of areas.

Until 2007, each CMOP director was responsible for acquiring the services and supplies the CMOP needed. CMOPs obtained contracting support primarily from local VISNs or VA medical centers. In 2007, PBM initiated significant changes in CMOP acquisition management. The National CMOP Office added a contracting and logistics section and centralized contracting. Each CMOP also hired a logistics manager to strengthen purchasing and inventory controls at the CMOP level. In December 2008, under the terms of a Memorandum of Understanding (MOU) between PBM and the VA Office of Acquisition and Logistics' National Acquisition Center (NAC), the National CMOP Office transferred the responsibility and staff for all CMOP contracting to the NAC.

The National CMOP Office has established a management review process for determining CMOP contract needs and evaluating the cost-effectiveness of procurement alternatives. A process and policy have been issued and the PBM Associate Deputy Chief Consultant for CMOP oversees the process. The NAC has procedures to assure compliance with the Federal Acquisitions and VA Acquisition Regulations. The CMOP has increased the number of trained Contracting Officers Technical Representatives (COTRs) from 37 to 75 to provide better contract oversight and ensure contractor performance. These changes will strengthen CMOP contract management and oversight functions and address findings in the OIG report.

Adverse Drug Event Reporting

Post-marketing drug surveillance is vital to reporting adverse drug events (ADEs) to the Food and Drug Administration (FDA) and VHA. A cornerstone of this approach is collecting and evaluating reports of ADEs through voluntary reporting by healthcare professionals. The safety profile of any drug or pharmaceutical evolves over time as new information is discovered when healthcare providers offer it to larger populations and sub-groups not previously studied during clinical trials. Because the electronic medical record is able to link prescription data to clinical outcomes at the patient level, VA is uniquely able to identify and track drug safety issues. VA has the only national system for electronic reporting of ADEs through its innovative VA Adverse Drug Event Reporting System (VA ADERS). By analyzing this computerized database, VA is able to identify drug safety signals, assess significance of external drug safety issues in our own patients, and track trends of known drug safety issues almost instantaneously.

Emergency Pharmacy Services

The Emergency Pharmacy Services section is responsible for procuring, storing, and maintaining emergency pharmaceutical and medical or surgical supply items for the VA Pharmaceutical Cache Program. This section works closely with the VA Office of Public Health and Environmental Hazards' Emergency Management Strategic Healthcare Group to ensure activation readiness of emergency supplies at VA Medical Center storage sites nationwide. In addition to maintaining VA's emergency pharmaceutical capabilities, Emergency Pharmacy Services staff can deploy VA's Mobile Pharmacies to provide local support in cases of national emergencies, such as a hurricane or other event, or in response to a pandemic disease, under the guidelines of VA's emergency response plan to ensure continuity of care and supplies to Veterans, no matter the circumstances.

National Formulary Management

In 2009, VA consolidated all of its formularies into a single VA National Formulary (VANF). The PBM office in Hines, Illinois, is the organizational entity responsible for coordinating the development, maintenance, and implementation of the VANF. Two groups, the VA Medical Advisory Panel (MAP) and the VISN Pharmacist Executives (VPE) Committee actively manage the VANF. The MAP provides clinical oversight of the formulary process and is comprised of practicing VA physicians, PBM clinical pharmacists and a physician from DoD. The VPE Committee is comprised of senior VISN pharmacists who represent each VISN Formulary Committee, a pharmacist from the Indian Health Service, and pharmacists from DoD; it provides both clinical and operational oversight of the formulary process.

PBM pharmacists support the MAP and VPEs by monitoring the medical literature, scientific research and VA outcomes data to identify evidence that may support adding drugs to or deleting drugs from the VANF and by drafting evidence-based prescribing guidance. VA develops guidance on the pharmacologic management of common and high-cost diseases and collaborates with clinical experts within the Department to develop or refine guidance when necessary. VA disseminates the guidance throughout the Department for peer-review prior to being presented to the MAP and VPEs for consideration. PBM has also developed mechanisms for system-wide collection, analysis, trending and reporting of ADEs.

PBM is also responsible for developing strategies for including a drug class under a National Contract and monitoring trends regarding product utilization with Pharmaceutical Prime Vendor purchases. Pharmacists from DoD, VA, the Indian Health Service, and the Bureau of Prisons discuss drug classes with potential for joint national contracting. VA representatives meet with manufacturers for selected drug classes and develop solicitation requirements for use by VA's NAC. PBM reviews manufacturer incentive proposals, coordinates price and clinical information as well as contractor performance when considering renewal options for multiyear contracts, and collaborates with VA contracting officers, counsel, acquisition review, and VA field personnel regarding contract issues.

VA's Formulary Management Process is stipulated in VHA Handbook 1108.08, "VHA Formulary Management Process," which was last updated on February 26, 2009. This document provides guidance to the Deputy Under Secretary for Health for Operations and Management, VA's MAP, the PBM Chief Consultant, VISN Directors, VISN Pharmacist Executives, Facility Directors, Facility Pharmacists, and VA prescribers.

VA Center for Medication Safety (VA MedSAFE)

PBM strives to ensure that Veterans receive the right medication, in the right dose, at the right time. VA's efforts for safe medication use are supported by the

Computerized Patient Record System (CPRS), electronic medication order entry, automated prescription fulfillment, and the Bar Code Medication Administration (BCMA) system. The electronic health record (EHR) currently provides automated checks for allergies and possible drug interactions, further improving patient safety and care. VA's Center for Medication Safety (VA MedSAFE) is a national, comprehensive pharmaco-vigilance program that emphasizes the safe and appropriate use of medications. VA MedSAFE utilizes different methods and tools, including passive and active surveillance, to continuously monitor for potential ADEs, including the use of VA ADERS as previously described.

An ADE is defined as an unintended effect of a drug that occurs secondary to drug administration. In many instances, VA MedSAFE directly and promptly notifies providers across VA's healthcare system if patients are at risk through its Risk Reduction efforts. VA, DoD and FDA have a MOU that allows close collaboration on specific post-marketing surveillance efforts and other drug and vaccine safety projects. These efforts are conducted through FDA's newly established Sentinel Initiative and its Office of Surveillance and Epidemiology's Center for Drug Safety and Epidemiology Research. Medications and prescriptions are essential to effective healthcare management, but inaccuracies can have severe repercussions.

Evaluating preventable ADEs, providing interventions to decrease preventable ADEs, and educating the field on best practices reduce the likelihood of ADEs occurring. By conducting and promoting medication safety projects at the regional and national levels, VA provides safe and effective pharmaceutical care to Veterans. Through the national roll-up system and data analysis provided by VA MedSAFE, each facility and VISN can benchmark themselves against national trends. We are unaware of any other healthcare system with as robust and well-developed a system for tracking, assessing and acting on drug-related safety issues within their patient population.

VA provides consumer medication information sheets on each new and renewed prescription. VA is highly engaged with patient education on medications, with local medical centers developing policy for teams of clinicians to provide medication education, involving physicians, nurse practitioners, physician assistants, clinical pharmacy specialists, pharmacists, nurses, and other allied healthcare providers. Clinical Pharmacy Specialists and clinical pharmacists are key members of the healthcare team and can assist in optimizing drug therapy and improving medication safety for outpatients.

Medication Reconciliation, a Joint Commission National Patient Safety Goal, is a process which mitigates the risk of ADEs that occur at transitions of care. It does this by addressing discrepancies between a patient's accounting of his or her medication use and the medication lists in the medical record every time a medication is dispensed, changed, or added to the medication regiment. There are many barriers to implementation including interoperability, software development, staff and organization adoption, and a changing Joint Commission National Patient Safety Goal.

The VA Medication Reconciliation Initiative, launched in December 2008, is tasked with facilitating safe, high quality, effective, and above all, Veteran-centered medication reconciliation throughout the VA system. This multidisciplinary effort includes a VA Medication Reconciliation Toolkit, Educational Video, Facility Monitor, External Peer Review Process, and patient informational Web site called "Medications: Play it Safe!" on the My Health*e*Vet Web site. This initiative's workgroups continue to improve patient and staff resources and tools to improve documentation and monitoring of this process. In the coming months, we will continue to bring together VA innovators with those in DoD and the private sector to establish a world-class medication reconciliation program for Veterans and to provide guidance for this challenging endeavor.

Conclusion

Mr. Chairman, VA has developed a remarkable pharmacy benefits management system that provides Veterans safe and effective medication to improve their healthcare. Our National Formulary is based on the best clinical research and leverages the size of our patient population and Department to procure medications at a low cost. Thank you again for the opportunity to testify. My colleagues and I are prepared to answer your questions.

Statement of American Federation of Government Employees, AFL–CIO

The American Federation of Government Employees (AFGE) appreciates the opportunity to present its views on veterans' pharmaceutical needs. AFGE represents approximately 180,000 employees in the Department of Veterans Affairs (VA), more than two-thirds of whom are Veterans Health Administration (VHA) professionals on the frontlines treating the physical and mental health needs of our veteran population.

Recruitment and Retention of VA Pharmacy Workforce

VHA ranks pharmacists third among the top ten occupations as national priorities for recruitment and retention. (See VHA's Workforce Succession Strategic Plan for FY 2008–2012, page 30). According to the VA's exit survey (page 34), career advancement is the most common reason for pharmacists to leave the VA, followed by compensation.

VHA, the Bureau of Labor Statistics and other public and private sources project a growing shortage of pharmacists nationwide due to employment growth, resignations and retirements. In order for VHA to effectively compete with other employers in the face of this worsening pharmacist shortage, it needs to ensure that all local facilities properly use special salary rates and other recruitment and retention incentives.

AFGE commends VHA for recent efforts by some medical center directors to address advancement and compensation barriers with national salary surveys, bonuses and other recruitment and retention incentives. However, whether any benefits of these national initiatives accrue to the individual pharmacist depends largely on the discretion of the local facility director. As a result, in a number of facilities, VA pharmacist salaries are significantly below salaries offered by other local employers.

Therefore, each facility should be required to align pharmacist salaries closely with national surveys and third party data, and update these salaries at least annually.

To retain older, experienced pharmacists, VHA should reevaluate its current policy of appointing new pharmacists with limited or no experience at a GS–12 level. These appointments are not supported by the Hybrid Title 38 qualification standards for pharmacists and hurt morale among more experienced pharmacists. VHA policy makes clear that qualification standards are not intended to address salary issues. Rather, VHA has various pay authorities, such as retention incentives, special salary rates and bonuses; because VHA is slow to utilize these pay authorities to react to community practice, chiefs of pharmacy are forced to upgrade pharmacists instead.

VHA should also evaluate the widespread practice of restricting certain positions to Doctors of Pharmacy ("PharmDs"). The pharmacist qualification standards give equal credit for education and experience. Unfortunately, some managers are unwilling to adequately credit experience despite these clear standards. The justification that managers rely on to require PharmDs is flawed, i.e. they contend that the VA Clinical Pharmacist position is comparable to positions in private sector retail establishments. However, they are not comparable; private sector clinical pharmacists more typically work "24/7" and weekend schedules.

With regard to Pharmacy Technicians, VA needs to increase the number of GS–6 positions for certified employees. Currently, management is not required to promote to a GS–6 because under the Pharmacy Technician qualifications standards, a GS–6 is above the "full performance" level.

VA should consider adding a requirement that all Pharmacy Technicians pass the Technician Certification (PTCB) test to be promoted to the GS–6 level. Certification requirements are prevalent in the private sector. Certification was part of the original intent of the Subject Matter Experts who developed the Pharmacy Technician qualification standard, and certification was also the understanding of the Hybrid Title 38 Collaboration Team and many of the members of the Professional Standard Boards. In addition, VA needs to republish the qualification standards allowing those who attain certification to be at the journeyman level. Having employees attain certification status and not be rewarded for this achievement is disheartening to say the least.

Pharmacy Staffing

Many AFGE members report inadequate staffing at their pharmacies. As a result, both pharmacists and pharmacy technicians are requested to work overtime on a regular basis. Pressure to work overtime on a prolonged basis can hurt workplace morale, increase risks to patients and is more costly to the taxpayer than expanding the workforce.

Understaffing can also have wider ramifications. For example, the Minneapolis VAMC has one of the busiest VA chemotherapy departments in the country. The facility recently built a chemotherapy satellite pharmacy that complies with new OSHA/NIOSH "negative pressure" regulations for preparing chemotherapy that were intended to reduce the risk of harmful exposure of IV room staff to hazardous substances. Even though the satellite was completed over a year ago, management has not filled the pharmacy department's request for an additional technician who is needed to work in the satellite, citing budget constraints. As a result, the facility has still not moved chemotherapy preparation to this satellite, and staff continues to prepare chemotherapy in a positive pressure room in violation of the new regulations.

Short staffing also limits the ability of the pharmacy workforce to comply with the large number of VA directives that are issued on a regular basis to improve patient care.

Another AFGE member reported that at her facility, the pharmacy does not have a triage pharmacist on staff that could extend maintenance medications until the next primary care appointment if the patient runs short.

AFGE members also expressed concern about the large number of pharmacists who only have clinical duties. In contrast, pharmacy production and verification functions, which involve extensive requirements for providing medications to patients, remain short staffed.

Other Comments

CMOPs

AFGE urges this Subcommittee to encourage the replication of best practices of ergonomic interventions in place at some Consolidated Mail Outpatient Pharmacies (CMOP's) to other CMOPs and hospital outpatient verification high production areas.

Formularies

AFGE pharmacist members expressed concern about the unintended impact of performance measures related to cost savings. In order to meet Performance Measures, facilities often switch medications from a drug in one class to another drug in the same class or a similar class. Frequent switching frustrates and confuses our veterans. It is also perplexing to staff why VHA allows so many deviations to the formulary by pharmacy benefit managers at the VISN level.

Members also pointed out problems that result from other hospital units using different products than the pharmacy. For example, the pharmacy formulary allows the use of one type of nutritional supplement for veterans who are outpatient, while the dietetic service has a separate contracting process and therefore uses another product for inpatient care. As a result, when a veteran changes from inpatient to outpatient status, there are continuity of care problems. Similarly, many of the wound care/dressing supplies provided by Supplies, Processing and Delivery (SPD) on an inpatient basis are different than those supplied by the pharmacy for outpatients. This also leads to confusion and coordination problems for clinicians and patients.

Information Technology

Members indicated a need for a number of IT upgrades; for example, it would be helpful to upgrade the VA intravenous (IV) package/IV labeling, and also to have IV pumps that could download infusion data into the computerized patient record system.

Patient Safety

AFGE urges increased oversight of the medication reconciliation process. The Center for Patient Safety should look closely at VHA's difficulties in complying with Joint Commission (JCAHO) performance criteria in this area, and the adverse impact of noncompliance on other inpatient staff members.

A pharmacist on another facility expressed concern about the practice of allowing contract nurses from the state nursing homes, rather than the veteran's treating physician, to make requests for medication refills without any accountability.

AFGE thanks the Subcommittee for the opportunity to provide input into this issue.

Statement of Hon. Cliff Stearns,
a Representative in Congress from the State of Florida

Thank you Mr. Chairman. I appreciate your holding this hearing to examine the management of the Department of Veterans Affairs (VA) pharmacy program.

The development of prescription medications that relieve suffering, prevent, cure, and help manage illnesses has revolutionized modern medicine and is improving the quality of life for many of our ill, injured and elderly veterans.

Last year, VA filled over 125 million prescriptions for veteran patients and expects that amount to double in 2010 to more than 254 million prescriptions.

In 1997, with the increased use of pharmaceuticals and concerns over rising drug costs and geographic variability, VA was prompted to establish a single National Formulary to help manage costs and improve consistency across the VA healthcare system. The National Formulary provides VA with leverage to purchase in bulk and increase the cost-effectiveness of VA's pharmacy program.

A formulary system has the potential to also help educate physicians and patients about drugs, ensure the use of quality drug products and promote evidence-based management of disease.

However, it can also generate serious concerns about quality of care because formularies restrict the different classes of drugs available. For instance, a drug on the list may not be effective for 100 percent of the patients or it could be unexpectedly discontinued. Additionally there is a lengthy process for the inclusion of a new or breakthrough drug, and there are questions about the fairness and responsiveness for the approval of the use of a non-formulary drug to meet the specific needs of a veteran patient.

VA's proper management of the formulary system is vital to ensuring our veterans receive the highest quality of care and access to the most up-to-date medications they deserve.

Today's hearing will explore these important issues, and I would like to thank all of our witnesses today for their testimony and I look forward to the hearing.

Thank you Mr. Chairman. I yield back the balance of my time.

MATERIAL SUBMITTED FOR THE RECORD

U.S. Department of Health and Human Services
Food and Drug Administration
Rockville MD.
November 6, 2009

Hon. Michael H. Michaud
Chairman
Subcommittee on Health
Committee on Veterans' Affairs
House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

This letter is in follow-up to the September 22, 2009, hearing entitled "Is the U.S. Department of Veterans Affairs (VA) Meeting the Pharmaceutical Needs of Veterans? An Examination of the VA National Formulary Issues of Patient Safety, and Management of the Pharmacy Benefits Program." During that hearing you asked how the Food and Drug Administration (FDA or the Agency) deals with complaints about conflict of interest. After receiving further clarification from your staff, below is our response your question, as it specifically pertains to potential conflicts of interest and FDA advisory committee panels.

FDA's advisory committees provide independent expert advice to the Agency on scientific, technical, and policy matter related to the development and evaluation of FDA-regulated products. Advisory committees enhance FDA's ability to protect and promote public health by ensuring it has access to advice, in a public manner, as permitted by existing laws and regulations. Although advisory committees provide recommendations to FDA, FDA makes the final decisions.

FDA's advisory committee program is governed by a number of Federal laws and regulations that set forth standards for convening advisory committees and reviewing potential conflicts of interest, among other things. FDA also has developed guidance documents that describe the Agency's recommendations and policy related to our advisory committees.

FDA is committed to strictly adhering to the laws and regulations governing the process for selecting advisory committee members. In August 2008, FDA implemented several improved policies and procedures to strengthen its management of advisory committees. These policies and procedures are detailed in the form of guidance documents and their goal is to make the process of seeking advice from independent experts as open, public and transparent as possible.

One guidance, *Procedures for Determining Conflict of Interest and Eligibility for Participation in FDA Advisory Committees*, describes how FDA determines whether an individual invited to participate in an FDA advisory committee has a potential conflict of interest and whether he/she is eligible to participate in an advisory meeting. The approach set forth in this guidance makes the Agency's review of potential conflicts of interest more stringent than current legal requirements and previous FDA guidance. For example, according to the new guidance:

- If an individual, their spouse, or minor child has potentially conflicting financial interests totaling more than $50,000, they would not ordinarily be allowed to participate in that meeting.
- Four specific scenarios are outlined where the conflict is significant and FDA does not intend to issue a waiver, even if the potential personal conflict is below $50,000.
- Before a waiver is issued, FDA will require a showing that the waiver is necessary to afford the committee essential expertise.
- FDA will limit the number of waivers that are granted, as is now required by law.

Another guidance, *Public Availability of Advisory Committee Members' Financial Interest Information and Waivers*, focuses on ensuring that when FDA grants a waiver, the circumstances of that waiver are made clear and transparent to the public. Therefore, all waivers and advisors' disclosures of potentially conflicting interests are posted to the FDA Web site. In most cases, FDA posts these documents at least 15 days prior to the relevant advisory committee meeting. These changes help to make the basis for FDA's decision to grant a waiver clearer to the public.

A fact sheet providing a detailed summary of each guidance is enclosed and can also be found on FDA's Web site at *http://www.fda.gov/ociadvisory/factsheet 080408.html*. These guidances enable FDA to improve consistency in the handling

of potential conflicts of interest and to provide greater clarity to the public. FDA makes the laws, regulations, and guidance documents pertaining to advisory committees available through our Web site at *www.fda.gov/advisorycommittees* to provide ready access to the statutory aid regulatory framework that FDA advisory committees operate within, and to describe the steps that FDA has taken to enhance decision-making, increase transparency, and strengthen public confidence in our advisory committee program.

Thank you for your interest in this matter. If you have further concerns, please let us know.

Sincerely,

Jeanne Ireland
Assistant Commissioner for Legislation

Enclosure:
Fact Sheet: "Improved Policies and Procedures Regarding Transparency, Public Disclosure for FDA Advisory Committees"

U.S. Food and Drug Administration
U.S. Department of Health and Human Services

Fact Sheet
Improved Policies and Procedures Regarding Transparency, Public Disclosure for FDA Advisory Committees

The Food and Drug Administration today announced several improved policies and procedures to strengthen its management of FDA advisory committees. They are detailed in four final guidance documents and one draft guidance outlined below. Our goal is to make the our process for seeking advice from independent experts as open, public, and transparent as possible, so that we maintain the highest public confidence in that process.

Final Guidance on Procedures For Determining Conflict of Interest and Eligibility for Participation in FDA Advisory Committees

This guidance describes how FDA will determine whether an individual invited to participate in an FDA advisory committee has a potential conflict of interest and, accordingly, whether he or she is eligible to participate in an advisory committee meeting. FDA has for many years screened prospective advisory committee participants to determine whether the potential for a financial conflict of interest exists. When an advisor has a potential conflict, FDA may grant a waiver to allow participation.

The approach set forth in FDA's guidance makes the agency's review of potential conflicts more stringent than the legal requirements recently put in place by Congress. It is more stringent than FDA's Waiver Criteria 2000 guidance in four ways:

- First, if an individual, his spouse, or minor child has potentially conflicting financial interests totaling more than $50,000, he or she would not be allowed to participate in that meeting.
- Second, the guidance specifies four scenarios where the conflict is significant and FDA does not intend to issue a waiver, even if the potential personal conflict is below $50,000. (For example, if the advisor is the principal investigator of a clinical trial of a product about which the committee will be providing advice, the advisor will not be allowed to participate in that meeting.)
- Third, before we issue any waiver, we will require a showing that the waiver is necessary to afford the committee essential expertise.
- Fourth, as now required by law, we will limit the number of waivers we grant.

The guidance will improve consistency in the agency's handling of potential conflicts of interest and provide greater clarity to the public.

Final Guidance on Public Availability of Advisory Committee Members' Financial Interest Information and Waivers

This guidance will ensure that when FDA grants a waiver, the circumstances of that waiver will be made clear and transparent to the public. All waivers and advisors' disclosures of potentially conflicting interests will be posted to the FDA Web site. In most cases, FDA will post these documents at least 15 days prior to the relevant advisory committee meeting. New templates for waivers and financial interest

disclosure will make them clearer and more consistent. These changes will make the basis for FDA's decision to grant a waiver clearer to the public.

Final Guidance on Voting Procedures at Advisory Committee Meetings

This guidance is intended to ensure integrity of the voting process at advisory committee meetings. It recommends that any question put to a vote be clearly and collectively understood by those voting, and it urges that there be a robust discussion of the issues at the heart of the question before voting takes place. The guidance also recommends that votes be cast simultaneously rather than sequentially. This is intended to avoid "voting momentum," in which voters may be influenced, even subconsciously, by the votes of those who precede them.

Final Guidance on Preparation and Public Availability of Information Given to Advisory Committee Members

This guidance is intended to help sponsors develop, prepare and submit to FDA briefing materials that will be given to advisory committee members as background information before an open FDA advisory committee meeting. It sets out timelines for preparing and submitting the briefing materials to FDA. The guidance also describes when FDA intends to make the briefing materials available to the public.

As described in the guidance, FDA intends to notify a sponsor about an open meeting that will involve its product approximately 55 business days before the meeting. The guidance then includes information on how to prepare its briefing materials, and sets out timelines for the submission, review, and public availability of the briefing materials. The timelines vary depending on whether the sponsor's briefing materials may include information that, under certain circumstances, could be considered to be exempt from public disclosure, or whether the sponsor is stating that its briefing materials are fully releasable to the public.

The guidance states that FDA intends to post the publicly available version of the briefing materials on its Web site no later than two full business days before the day the meeting is scheduled to occur.

Draft Guidance on When FDA Convenes an Advisory Committee

This draft guidance proposes to clarify when FDA should refer a matter to an advisory committee. It is being issued for consideration and public comment.

In some instances, FDA is required by law to refer an issue to an advisory committee. In others, it has discretion to consider whether to refer a matter to an advisory committee. The guidance proposes that FDA consider three factors when deciding whether to voluntarily refer a matter to an advisory committee. It proposes that when one of these factors is met, FDA should refer the matter to an advisory committee. Conversely, if none of the factors is met, FDA should not refer the matter.

The guidance also proposes that, for all first-of-a-kind or first-in-class products for human use, FDA either refer the product to an advisory committee or provide in the action letter for that product a summary of the reasons why it did not refer the product to an advisory committee before approval.

Web Site Improvements

FDA has enhanced the transparency of its advisory committee program by overhauling its advisory committee Web site. We began by engaging various stakeholder groups—including consumers, patients, healthcare professionals, and industry representatives—to help us assess the Web site's strengths and weaknesses.

Based on this assessment, we redesigned the Web site and streamlined access to the information that appears to be of greatest interest to users. We then performed usability testing to evaluate the changes and to further refine our improvements.

The most significant improvements include the following:

- Meeting announcements will be posted in an easy to read format that provides prominent information on the page and allows for quick access to other meeting information in an organized fashion.
- Past meeting information, which was difficult to find on the original site, is easily accessible from the main page.
- Meeting materials are now posted in one location, removing the previously difficult process of finding, or not finding, information via a multitude of ill-defined links.
- Each committee will have one location that provides full information on that committee—its Charter, Roster, steps for nominating candidates for committee vacancies, past meeting information, and who to contact with questions about the committee.
- A new section titled "Most Popular" links will highlight significant areas of public interest.

- The page offers an opportunity for consumers to provide feedback on the site our advisory Committees—and we'll post summaries of that feedback.

http://www.fda.gov/oc/advisory/factsheet080408.html

Committee on Veterans' Affairs
Subcommittee on Health
Washington, DC.
October 1, 2009

Honorable George J. Opfer
Inspector General
Office of Inspector General
U.S Department of Veterans Affairs
801 I Street, NW
Washington, DC 20001

Dear Inspector General Opfer:

Thank you for the testimony of Belinda J. Finn, Assistant Inspector General for Audits and Investigations at the U.S. House of Representatives Committee on Veterans' Affairs, Subcommittee on Health Oversight Hearing on "Is the VA Meeting the Pharmaceutical Needs of Veterans? An Examination of the VA National Formulary, Issues of Patient Safety, and Management of the Pharmacy Benefits Program." that took place on September 22, 2009.

Please provide answers to the following questions by November 12, 2009, to Jeff Burdette, Legislative Assistant to the Subcommittee on Health.

1. Do you believe that the VA has derived sufficient benefit from the centralizing of contracting responsibilities at the National CMOP office? In other words, does the national CMOP remain the preferred model for acquiring pharmaceutical supplies and services?
2. In addition to the VA issuing and enforcing policies to improve accountability of non-controlled drugs, what additional tools does the VA need for effective enforcement of the new policies? For example, Ms. Finn's testimony noted the need to improve IT. Are there other tools that the VA needs to acquire?

Thank you again for taking the time to answer these questions. The Committee looks forward to receiving your answers by November 12, 2009.

Sincerely,

MICHAEL H. MICHAUD
Chairman

U.S. Department of Veterans Affairs
Office of Inspector General
Washington, DC.
November 12, 2009

Hon. Michael H. Michaud
Chairman
Subcommittee on Health
Committee on Veterans' Affairs
United States House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

This is in response to your October 1, 2009, letter following the September 22, 2009, hearing on *Is the VA Meeting the Pharmaceutical Needs of Veterans? An Examination of the VA National Formulary, Issues of Patient Safety, and Management of the Pharmacy Benefits Program.* Enclosed is our response to the additional hearing questions. This information has also been provided to Congressman Henry E. Brown, Jr., Ranking Republican Member, Subcommittee on Health.

Thank you for your interest in the Department of Veterans Affairs.

Sincerely,

GEORGE J. OPFER
Inspector General

Enclosure

[An identical letter was sent to Hon. Henry E. Brown, Jr., Ranking Republican Member, Subcommittee on Health, Committee on Veterans' Affairs.]

Questions for the Honorable George J. Opfer, Inspector General, U.S. Department of Veterans Affairs, Before the Subcommittee on Health, Committee on Veterans' Affairs, United States House of Representatives Hearing on *Is the VA Meeting the Pharmaceutical Needs of Veterans?*

Question 1: Do you believe that the VA has derived sufficient benefit from the centralizing of contracting responsibilities at the National CMOP Office? In other words, does the national CMOP remain the preferred model for acquiring pharmaceutical supplies and services?

Response: The VA's National Acquisition Center (NAC) is responsible for purchasing pharmaceuticals, supplies, and services dispensed by the national community mail outpatient pharmacies (CMOPs). Centralizing this function provides VA the following benefits:

- Opportunities to leverage buying power to obtain lower prices and volume discounts.
- Decrease in the potential for conflict of interest situations by having independent contracting actions.
- Creation of a professional acquisition staff dedicated to supporting pharmaceutical contract initiatives.
- Improvement in the compliance with the Federal Acquisition Regulation and VA Acquisition Regulation.

The CMOP is a preferred model for dispensing pharmaceutical supplies and services because automation allows for safety in the dispensing of pharmaceuticals and it is less expensive due to better drug pricing and greater efficiencies realized by relying on seven CMOPs as opposed to individual VA medical centers and clinics.

Question 2: In addition to the VA issuing and enforcing policies to improve accountability of non-controlled drugs, what additional tools does the VA need for effective enforcement of the new policies? For example, Ms. Finn's testimony noted the need to improve IT. Are there other tools that the VA needs to acquire?

Response: In our report, *Audit of the Veterans Health Administration's Management of Non-Controlled Drugs* (June 23, 2009), we identified several weaknesses in the Veterans Health Information System and Technology Architecture (VistA)—the information system the Veterans Health Administration (VHA) uses to manage pharmacy services at its medical facilities. The current VistA system cannot provide information to accurately account for a facility's on-hand drug inventory.

In 2003, VHA launched the Pharmacy Re-Engineering (PRE) project to make improvements to VistA. We did not evaluate the design of the project or results of system tests, but Pharmacy Benefits Management officials told us that this new system is expected to address VistA deficiencies. The PRE project was halted as part of VA's Office of Information and Technology's review of VA system development projects, and has not yet fully restarted. Other IT systems or tools that would improve accountability over inventories include centralization of billing and drug file management, and Radio Frequency Identification (RFID) labeling for pharmaceuticals.

During our recent audits, the Pharmacy Benefits Management Services indicated that they would like to see the creation of specialty CMOPs. Currently, each CMOP manages many low volume products. By centralizing the low volume products, a specialty CMOP can bring the volume of those products up to a higher level and eliminate the distribution of those products at other CMOPs; potentially enabling CMOPs to manage inventory better. To recognize these improvements, CMOPs also need more robust software for billing customers. A system is needed where the CMOP that fills and bills for the prescription is transparent to the medical center.

For drug file management, there is currently little standardization of stock across the system. Improvements could be realized by standardizing stock lists and prices. Currently, CMOPs attempt to maintain prices on several thousand line items of inventory and predictably inventory information is not accurate at given points in

time. Managing the CMOP stock list centrally would enable CMOPs to vastly improve their drug file management and allow them to follow the private industry model where prices are pushed out to each CMOP from a central location.

The use of a RFID chip inside labels would enable CMOPs to electronically track stock from the time it came into their facilities until the time it left. If CMOP suppliers and United States Postal Service used this same technology, CMOPs could track drugs through the entire supply chain right up to the point where they reach the patient. Currently, costs appear prohibitive, but RFID pricing technology seems to be decreasing rapidly and VA should leverage future inventory management tools that enable the tracking and accountability for drugs through the entire supply chain.

Committee on Veterans' Affairs
Subcommittee on Health
Washington, DC.
October 1, 2009

Honorable Eric K. Shinseki
Secretary
U.S. Department of Veterans Affairs
810 Vermont Avenue, NW
Washington, DC 20240

Dear Secretary Shinseki:

Thank you for the testimony of Michael Valentino, Chief Consultant to the Pharmacy Benefits Management Service at the U.S. House of Representatives Committee on Veterans' Affairs, Subcommittee on Health Oversight Hearing on "Is the VA Meeting the Pharmaceutical Needs of Veterans? An Examination of the VA National Formulary, Issues of Patient Safety, and Management of the Pharmacy Benefits Program." that took place on September 22, 2009.

Please provide answers to the following questions by November 12, 2009, to Jeff Burdette, Legislative Assistant to the Subcommittee on Health.

1. How are new drugs added to the VA national formulary? How are requests from VISNs and local facilities to add new drugs to the formulary handled? How often is the national formulary updated and when was the last update?
2. It is our understanding that each VA facility must institute a process to review requests for drugs that are not on the formulary. What are the respective roles of the VA medical center, VISN, and the VA central office in ensuring that the review process for non-formulary drug requests are not subjective and based on objective criteria?
3. What percent of non-formulary drug requests are approved? If such requests for non-formulary drugs are not approved, what are some typical reasons for the non-approval? Does the VA track and store data on non-formulary drug requests?
4. In 2000, a report by the Institute of Medicine found that the VA's national formulary lacked "essential systems to assure that new drugs are expeditiously reviewed." Please discuss the steps that the VA has taken to address this deficiency.
5. How does the VA handle issues of patient safety and prevent adverse drug interactions for veterans who fill their prescriptions through the VA and private pharmacies?
6. What is the VA doing to encourage medication compliance among veterans to maximize the results of the drug therapy?
7. The VA's November 2002 directive on "VA National Dual Care Policy" expired in July 2007. Have there been any updates to the directive? If not, are there plans to issue an updated directive?
8. Since the VA developed an integrated Web-based application that fully automates the VA's adverse drug event reporting process, has the reporting increased? If so, by how much? What does the VA do with this data? Who reviews the reports and what action, if any, is taken? For example, are there a certain number of adverse drug events that are reported before the VA releases guidance?
9. Please describe the work and role of the VA Center for Medication Safety. For example, what are some examples of the medication safety projects that this Center implements? How does the Center educate the field on safe and best

practices to minimize adverse drug events? What are some examples of the research that the Center has translated into national policy?

10. Please describe the VA's interactions with FDA on drug recalls. Does the VA follow the FDA's lead? Or, does the VA have the authority to halt the use of the prescription drugs by the veterans before FDA officially initiates the recall?
11. As you know, off-labeling is use of drugs outside of the approved indications by FDA. How prevalent are off-label prescriptions at the VA? And how does the VA deal with off-label drug use in cases where there is little or not supportive evidence of benefit or safety in a population or for a medical condition?
12. It is our understanding that some VA facility directors confer prescribing authority to certain nurses, pharmacists, and physician assistants if the state provides this authority and if it is cosigned by a medical doctor. What guidance and oversight is provided by the central VA office?
13. Based on the findings of the Inspector General's June 2009 audit reports, what steps has the VA taken to address issues identified with the management of non-controlled drugs and the CMOP contract?
14. Why did the VA allow the directive on Drug Accountability Software to lapse in 2003? Are there plans for an updated directive?

Thank you again for taking the time to answer these questions. The Committee looks forward to receiving your answers by November 12, 2009.

Sincerely,

MICHAEL H. MICHAUD
Chairman

Questions for the Record
The Honorable Michael H. Michaud, Chairman
House Committee Veterans' Affairs, Subcommittee on Health
Is the U.S. Department of Veterans' Affairs (VA) Meeting the Pharmaceutical Needs of Veterans? An Examination of the VA National Formulary, Issues of Patient Safety, and Management of the Pharmacy Benefits Program
September 22, 2009

Question 1: How are new drugs added to the VA national formulary? How are requests from VISNs and local facilities to add new drugs to the formulary handled? How often is the national formulary updated and when was the last update?

Response: The Department of Veterans' Affairs (VA) policy (http://vaww1.va.gov/vhapublications/ViewPublication.asp?pub_ID=1834) requires that drugs newly approved by the Food and Drug Administration (FDA) be automatically reviewed for VA National Formulary (VANF) as soon as sufficient safety and efficacy information becomes available. In addition, requests for changes in a VANF drug status may be submitted to the pharmacy benefits manager (PBM) by a Veterans Integrated Service Network (VISN) formulary committee, the VISN pharmacist executive committee (VPE), the Medical Advisory Panel (MAP), a Veterans Health Administration (VHA) Chief Medical Consultant, or a VHA Chief Medical Officer. An individual or group of physicians may submit a request for VANF addition through its VISN Formulary Committee(s). Decisions for VANF listing are evidence-based and made by consensus of the MAP and VPE Committees. The VANF is updated monthly, provided that there are changes to be posted. The last two formulary updates occurred on July 1, 2009, and October 7, 2009.

Question 2: It is our understanding that each VA facility must institute a process to review requests for drugs that are not on the formulary. What are the respective roles of the VA medical center, VISN, and the VA central office in ensuring that the review process for non-formulary drug requests are not subjective and based on objective criteria?

Response: VA policy requires that a non-formulary request process exist at each VA medical center (http://vaww1.va.gov/vhapublications/ViewPublication.asp?pub_ID=1834).

This policy is intended to assure that decisions are evidence-based and timely. Routine requests for non-formulary agents are reviewed and the requestor is notified of the decision within 96 hours of receipt of a completed non-formulary request. Emergency requests for non-formulary agents are immediately addressed by individual(s) identified in local VA medical center policy. If the degree of urgency or

emergency is in question, the drug is provided immediately and the nature of the urgency or emergency is reviewed afterward.

Non-formulary drugs that have received FDA approval are only to be approved when:

1. A documented contraindication exists to the formulary agent(s)
2. A documented adverse reaction occurred to the formulary agent(s)
3. A documented therapeutic failure to formulary therapeutic alternatives exists
4. No formulary alternative exists
5. The patient has previously responded to a non-formulary agent and serious risk is associated with a change to a formulary agent; or
6. Other circumstances having compelling evidence-based clinical reasons

All physician-initiated appeals of a non-formulary drug request are received and adjudicated by the facility chief of staff.

Medical center management, VISN pharmacist executives (VPE) and VA Central Office Pharmacy Benefits Management (PBM) Service staff have the responsibility to assure the intent of the VA policy is followed. Quarterly reports from VPEs are sent to the PBM Service. These reports show the number of non-formulary requests received, approved and denied, and the average processing time. Evidence-based prescribing guidance documents, when applicable, are the objective criteria used to assist clinicians in the non-formulary review process.

Question 3: What percent of non-formulary drug requests are approved? If such requests for non-formulary drugs are not approved, what are some typical reasons for the non-approval? Does the VA track and store data on non-formulary drug requests?

Response: Approximately 81 percent of non-formulary drug requests are approved. PBM does not track reasons for the non-approval of requests, however, a typical reason is due to clinicians not being aware of a suitable formulary alternative, particularly in the situation of medical trainees. Other common reasons include requests for off-label indications where there is no evidence to support safety and efficacy for the intended indication, and indications falling outside of VHA's evidence-based clinical criteria for use. Clinicians are able to ask for adjudication of any denial, if they disagree with the initial non-approval of the drug. PBM does track and store data regarding the number of non-formulary drug requests received, approved and denied, and the average process time for adjudicating the requests.

Question 4: In 2000, a report by the Institute of Medicine found that the VA's national formulary lacked "essential systems to assure that new drugs are expeditiously reviewed." Please discuss the steps that the VA has taken to address this deficiency.

Response: At the time the Institute of Medicine (IOM) conducted its review of the VA National Formulary, the addition of new drugs to the VANF was governed by VHA Directive 97–047 "VA National Formulary Policy." Paragraph 2.d. of this policy stated, "*PBM Formulary recommendations will be based on a review of new drug products approved by the Food and Drug Administration (FDA) and recommendations by VISN formulary committees. For a new drug product to be considered for addition to the Formulary, it must be on the market for a minimum of 1 year. Exceptions can be made if the FDA designates the product as a unique therapeutic entity (FDA designation of '1P').*" This policy was instituted as a safety precaution because many new drugs were being fast tracked through the review process and adequate clinical trials, in our patient population, were not always available. This 1 year period allowed for adequate evaluation of these agents in our patient population.

Directive 97–047 did not preclude VHA from reviewing new drugs expeditiously; it only prevented VHA from adding them to the VA National Formulary for 1-year after they reached the market unless they were approved by the FDA with a 1P designation. It is important to note that individual VISNs and facilities were not held to this policy for drug formularies managed at the local and VISN levels. They could, and did, add new drugs to VISN and facility formularies before the 1-year waiting period. It is also important to note that not all newly approved drugs are relevant to the VA population and would not be expected to be reviewed nor added to the formulary. Drugs used exclusively in the pediatric population are one example where the drugs would be neither extensively reviewed nor added to the formulary.

VHA advised IOM staff at the time they began their analysis that based on PBM's own review of existing formulary policy, it had decided to change the 1-year moratorium and eliminate that requirement from PBM policy. Although one of the hearing panelists stated that VA's 1-year moratorium policy is still in effect, that is not the case; it was eliminated in July 2001.

From 2001 through 2009 all policy governing VA Formulary practice was contained in VA Manuals, VHA Directives and PBM Policies; modified to accommodate changes. The National Formulary was a "core formulary" to which each VISN was permitted to supplement with local additions.

In an effort to ensure that a travelling veteran could obtain a needed refill or renewal of a scheduled medication at any VA location, the VISN Pharmacist Executives and the Medical Advisory Panel decided to do away with VISN variation and establish a comprehensive National Formulary; to which additions at the local level are no longer permitted. Therefore, on February 26, 2009, VHA published a Handbook (VHA Handbook 1108.08, "VHA Formulary Management Process") which provided a comprehensive document encompassing all prior policy; including changes implemented subsequent to the IOM analysis. Note: Under each formulary process the ability of the provider to request a medication via a *Non-formulary Request* (with an approval rate of 80 percent) was available. This accounts for approximately 4 percent of total prescriptions dispensed by VHA.

Question 5: How does the VA handle issues of patient safety and prevent adverse drug interactions for veterans who fill their prescriptions through the VA and private pharmacies?

Response: VHA's current drug-drug interaction (DDI) software package is available at the point of care to warn against potential critical and significant drug-drug interactions when a provider enters an outpatient prescription to be filled in a VA pharmacy. Potential interactions are communicated to prescribers as an Alert. Prescriptions obtained outside VA are recorded in the "non-VA medication" field in the computerized patient record system (CPRS) as part of the medication reconciliation process or when at the patient's request, a VA prescriber writes a prescription for the patient to fill at his or her expense at a non-VA pharmacy. The CPRS can provide order checks for medications dispensed by a VA pharmacy, or those documented as dispensed from a non-VA pharmacy when the drug is matched to VA's national drug file. Prescribers are required to state an "override reason" when submitting an order containing a critical drug-drug interaction for which they receive an Alert. Drug-drug interactions for non-VA medications are subject to additional manual screening by a pharmacist during the final order review. Any potential interactions identified during the final manual review are communicated to the prescriber.

Question 6: What is the VA doing to encourage medication compliance among veterans to maximize the results of the drug therapy?

Response: Medication compliance and monitoring is performed by clinical pharmacists, nurses and providers and discussed with patients during outpatient visits. These reviews evaluate the dose and schedule of each medication the patient is currently taking and are performed by clinicians throughout VA. Compliance is assessed by asking the patient about their medications through a series of questions and evaluating prescription refill patterns. It is always important to ask patients if they are having difficulty remembering to take their medications and VA believes clinical pharmacists are integral to the healthcare team to identify these types of barriers to compliance. For some patients, there may be an opportunity to reduce the medication burden (i.e. polypharmacy) to increase compliance. For others with a significant number of prescriptions, compliance may be increased through the use of assistive devices such as pill boxes, personalized medication schedules etc., which VA can provide.

CPRS version 26, released in May 2006, introduced new graphing features that are available to providers. Medication compliance can be charted in a graph with indications of prescription dispensing events, prescription days supply, and any relevant corresponding laboratory results for the patient. This allows a visual representation of when a patient can be reliably expected to have or have had a supply of medication on-hand.

Overall, medication compliance and monitoring is assessed and monitored on an ongoing case-by-case basis via numerous mechanisms (patient interviews, chart reviews and refill record reviews). Medication education and adherence is a shared responsibility among patients and their healthcare providers. Clinical pharmacists are extensively trained to assist patients with medication adherence and are available throughout VA's facilities to provide this service.

Question 7: The VA's November 2002 directive on "VA National Dual Care Policy" expired in July 2007. Have there been any updates to the directive? If not, are there plans to issue an updated directive?

Response: VA reissued the directive entitled, "VHA National Dual Care Policy" on August 25, 2009 (http://vaww1.va.gov/vhapublications/ViewPublication.asp?pub__ID=2058).

Question 8: Since the VA developed an integrated Web-based application that fully automates the VA's adverse drug event reporting process, has the reporting increased? If so, by how much? What does the VA do with this data? Who reviews the reports and what action, if any, is taken? For example, are there a certain number of adverse drug events that are reported before the VA releases guidance?

Response: VHA implemented its Web-based Veterans adverse drug event reporting system (VA ADERS) in March 2007. The legacy adverse drug event (ADE) system was used for reporting all serious ADEs prior to the implementation of VA ADERS. The increased reporting provides a more comprehensive assessment of adverse effects within the "veteran population." This in turn allows for increased vigilance and a more rapid response when concerns about therapy in this specific population are evidenced.

Due to the labor intensive process involved in coding ADE reports in the legacy system, only serious ADEs were required to be reported. The Web-based system automates coding of ADEs which allows for both non-serious and serious ADEs to be reported. The total number of ADEs reported in the legacy ADE database, which was in place from Fiscal Year 2001–2006, was 21,357. Since the implementation of VA ADERS in the 3rd quarter of FY 07 to the present, there have been 115,398 ADEs reported. This is 5 times more ADE reports in approximately half the time. The number increases to 9 times more ADE reports if an equal timeframe is used (FY 2004–2006: 12,855 reports) for a more direct comparison of ADE reports in VA ADERS to the number of ADE reports in the legacy ADE system. It is evident that the number of reported ADEs increased significantly as a result of the Web-based ADE system. This does not imply that more ADEs are occurring; it is only proof that the number of reports has increased, presumably due to ease of entry and staff education.

The data reported in VA ADERS is used for benchmarking reportable ADEs, assessing preventable ADEs, delineating between ADEs caused by the inherent pharmacology of a drug, drug-drug interactions, or idiosyncratic mechanisms. Standard reports such as the top 10 ADEs, top 10 drugs related to ADEs, the number of ADEs reported for new drugs, and ADEs reported to the FDA's MedWATCH program are tracked daily and reported nationally on a quarterly basis. In addition to the standard reports conducted by the VA ADERS team, ad hoc evaluations and reports are conducted as requested and placed on a predetermined reporting schedule (i.e. influenza ADEs are identified and reported weekly). The ad-hoc ADE reports are often conducted in response to a Risk Communication released by the FDA, a therapeutic or generic conversion taking place across the system, a cluster of ADEs reported in a given facility or VISN, an unexpected ADE report from a given site or in response to national safety campaign (i.e. influenza and antiviral use).

The reports are reviewed at the facility, VISN, and national levels. The national standard reports are reviewed by the VA ADERS team, the VA ADERS Advisory Committee and the Directors of VAMedSAFE. This information is assessed by the VA ADERS team and other staff from VAMedSAFE on a quarterly basis, or more frequently if needed. The VISN and facility reports are reviewed and assessed monthly by the facility Pharmacy & Therapeutics Committee (P&T) and the VISN Formulary Committees. The actions taken are in direct association with the problem identified. Examples include:

- Facility example: In response to an ADE resulting in an interaction between an anticoagulation drug that requires frequent therapeutic monitoring and another drug, the facility instituted a process to notify anticoagulation providers when patients are prescribed critically interacting drugs by another provider.
- VISN example: Dermatology staff identified that ADEs were occurring when topical steroid products were applied liberally. The term "liberally" was removed from the ordering process and replaced with "sparingly" and "lightly". By removing liberally as an option, providers can no longer inadvertently order the inappropriate directions that were contributing to the ADEs.
- National example: A review of a few serious ADEs related to intravenous iron dextran products led to the removal of one of the iron dextran formulations from the National VA Formulary.

The three examples above illustrate how actions taken in response to ADE reports occur at the facility, VISN, and national levels. The VA ADERS system is a dynamic system used for benchmarking, surveillance and process system improvements, all of which require different types and degrees of actions depending on the level and seriousness of the event. There is no "threshold" or "preset ADE number" that dictates a guidance release; however, medication safety is inherent in the VA pharmacy culture and results and reports from this system are used on a regular basis to aid in process improvements that enhance patient safety at the facility or VISN

level, add to information at a national level to assist in Drug Safety Risk Communications and informed decisions, and lastly, serve as a foundation for developing national safety based Medication Use Evaluations (MUE).

Question 9: Please describe the work and role of the VA Center for Medication Safety. For example, what are some examples of the medication safety projects that this Center implements? How does the Center educate the field on safe and best practices to minimize adverse drug events? What are some examples of the research that the Center has translated into national policy?

Response: The VA Center for Medication Safety (VAMedSAFE) is a world-class comprehensive pharmacovigilance program. Pharmacovigilance is defined as the science of the detection, assessment, understanding and prevention of the adverse effects of drugs. VAMedSAFE has implemented many national projects to improve drug safety in the Veteran population. VAMedSAFE is recognized nationally for its efforts in drug safety and as a result has entered into a collaborative agreement with the FDA to evaluate the significance of known ADEs, and to identify and track new and emerging drug safety issues. As such, VAMedSAFE conducts drug safety and monitoring efforts with the rigor of a regulatory body, while maintaining the access and utilization required for a healthcare delivery system to take necessary action. The work of VAMedSAFE not only informs VA policy at the national level, but has been influential in many FDA decisions, hence affecting the U.S. population as a whole.

VAMedSAFE accomplishes its goals by evaluating preventable ADEs through the use of active and passive surveillance techniques, providing interventions to decrease preventable ADEs through Risk Reduction programs, educating clinical staff about medication safety best practices, advising clinical staff about emerging safety issues through Medication Safety/Risk Communications, and conducting and promoting medication safety research. Examples of VAMedSAFE projects include:

- Rapid Cycle Evaluations—This method uses integrated clinical and administrative databases and mining of spontaneously reported ADEs (through VA ADERS) to identify and assess the rate and risk of ADEs for specific medications. Selected examples include:
  - Flouroquinolones and dysglycemia
  - Safety of non-steroidal anti-inflammatory drugs (NSAIDs) in VA System in regard to the risk of myocardial infarction
  - Risk of thiazolidinediones and cardiovascular disease
  - Long-acting opioids and all cause mortality (focus on methadone)
- Risk Reduction Projects—Risk Reduction is the method used by VAMedSAFE to identify and intervene on potential ADEs. Selected examples include:
  - Nifedipine IR for hypertension
  - High dose vitamin E for cardiovascular disease prophylaxis
  - Glyburide use in elderly patients with renal insufficiency
  - Use of high dose zolpidem IR
- National Medication Use Evaluations (MUEs)—VAMedSAFE conducts national MUEs to evaluate and monitor the safe and appropriate use of agents across the VA system. Selected examples include:
  - Pravastatin vs Fluvastatin—Evaluation of safety and appropriate use following therapeutic interchange
  - Travoprost—Evaluation of safety following a therapeutic interchange
  - Erythropoesis—Stimulating Agents (ESAs)—Evaluation of appropriate monitoring to assure safe and cost-effective use of ESAs.

To minimize adverse drug events, VAMedSAFE educates the field on safe and best practices through safety bulletins, safety information documents attached to risk reduction efforts and continuing education programs. In FY 2009, thirty Safety Bulletins were disseminated to the field. VAMedSAFE develops many bulletins elaborating on or clarifying early warning communications and other warnings from FDA; however, many safety bulletins are developed secondary to ADE signals identified through VAMedSAFE's surveillance efforts or through direct reports and concerns from the field. Selected examples include:

- Safety Bulletins
  - Risk of Severe Hypoglycemia with Glyburide in Patients with Renal Insufficiency
  - Iron Dextran and the ADEs associated with the high molecular weight formulation
  - Concentrated opioid solutions and concentration/confusion problems
  - Oxybutynin and oxycodone Look-Alike Sound-Alike (LASA) errors

VAMedSAFE promotes, conducts and assists other researchers with medication safety research projects designed to evaluate safety signals or confirm suspected ADE signals. These studies often give VA needed information to make informed formulary management decisions. Selected examples of VAMedSAFE research projects that have been translated into national policy or resulted in formulary management decisions include:

- Thiazolidinediones and risk of myocardial infarction—This full study resulted from a Rapid Cycle Evaluation which was conducted in response to an FDA warning. The results of the study led to removal of a drug from the VANF and a revision of VA's prescribing criteria for this drug class.
- Fluoroquinolones and risk of dysglycemias—This study was conducted in response to a Rapid Cycle Evaluation that identified an ADE signal for severe dysglycemias with fluoroquinolones. The results of the study confirmed the suspected severe dysglycemia associated with some of the agents in the drug class. VA modified its prescribing criteria due to this study. Gatifloxacin utilization decreased substantially secondary to evaluations and recommendations in the prescribing criteria. VA's actions occurred 2 years prior to FDA recommending removal of the drug from the U.S. market.
- NSAIDs and the risk of myocardial infarction (MI)—This study resulted from a Rapid Cycle Evaluation that confirmed a cardiovascular ADE signal for the Cox-2 inhibitor drug class (a known ADE) and identified the absence of an ADE signal for some of the other NSAIDs. The results of the study further confirmed the risk of MI's with the Cox-2s and supported the safety of etodolac, the agent chosen as the recommended replacement for Cox-2s in VA.

Question 10: Please describe the VA's interactions with FDA on drug recalls. Does the VA follow the FDA's lead? Or, does the VA have the authority to halt the use of the prescription drugs by the veterans before FDA officially initiates the recall?

Response: The VA National Center for Patient Safety (NCPS) Product Recall Office (PRO) has organizational responsibility for all product recalls (including drug recalls) which involves identifying and removing recalled products from inventory. The PBM Services office has responsibility for reviewing all drug safety information including drug recalls, and developing Drug Safety Alerts when appropriate. PBM Services collaborates with NCPS PRO when drug recalls require contacting patients and replacing their supply of medication. NCPS PRO and PBM generally follow FDA's lead; however, PBM may determine that a drug recall should be considered "patient level" when the manufacturer and FDA have only recalled a drug to the "retail" level. VHA is not averse to initiating action ahead of or separate from FDA in order to provide enhanced drug safety for Veterans.

VHA frequently has advance notice on planned announcements by FDA concerning drug safety. As part of the VA–FDA MOU, PBM is given the opportunity to review and comment on FDA announcements days in advance. In addition to providing input to FDA, VA has the opportunity for advance planning to respond to drug safety issues, including drug recalls. In FDA's testimony, they highlighted one example (propoxyphene) where a drug recall was being considered, and VA provided important clinical information that was used in their regulatory decision-making process. Another example where VA worked closely with FDA on a drug recall was with contaminated un-fractionated heparin.

Question 11: As you know, off-labeling is the use of drugs outside of the approved indications by FDA. How prevalent are off-label prescriptions at the VA? And how does the VA deal with off-label drug use in cases where there is little or no supportive evidence of benefit or safety in a population or for a medical condition?

Response: VA PBM has provided guidance for the off-label use of medications (http://www.pbm.va.gov/directive/Guidance%20Off%20Label%20Prescribing.pdf).
PBM uses evidence-based medicine to inform formulary and coverage decisions. Thus, if there is adequate evidence of sufficient quality for the safe and effective use of a medication for an off-label indication, VA may support use of that drug for that particular indication. It should be noted that other factors play a part in this decision, most important being the consideration of other therapeutic interventions or medications that are available to treat the same condition.

When there is little or no evidence to support safety and efficacy for an off-label indication, decisions of coverage need to be decided on a case-by-case basis. In most circumstances, this requires consultation with the local Pharmacy and Therapeutics Committee, which can review the unique circumstances involved in the request. While there may be many situations where off-label use of medications is likely to benefit an individual patient, it should also be understood that there are many other

examples where off-label use of medications has been associated with patient harm. VA's guidance document gives direction for making those difficult decisions.

Question 12: It is our understanding that some VA facility directors confer prescribing authority to certain nurses, pharmacists, and physician assistants if the state provides this authority and if it is cosigned by a medical doctor. What guidance and oversight is provided by the central VA office?

Response: Under the principle of Federal Supremacy, VHA grants the authority to prescribe non-controlled substances to Advanced Practice Nurses, Clinical Pharmacy Specialists, and Pharmacists with direct patient care responsibilities and Physician Assistants. VHA grants the authority to prescribe controlled substances only to those providers whose State licensure permits this practice. This may take the form of a clinical privilege statement or a Scope of Practice, as appropriate. Privileging or scope of practice for every individual is reviewed by the relevant facility service chief, whose recommendation is submitted to the appropriate facility-based body. For privileges, the recommendation, along with the appointment recommendation of the Professional Standards Board (PSB) or credentialing committee (if applicable), is submitted to the medical staff's Executive Committee for review. The medical staff's Executive Committee evaluates the applicant's credentials to determine if clinical competence is adequately demonstrated to support the granting of the requested privileges. A final recommendation is then submitted to the facility Director for approval. For scope of practice statements, the service chief's recommendation is submitted for final approval to the facility-based authorizing body appropriate to each profession.

VHA has issued Directives on each of the professional groups identified in the question that outline the approval process for prescriptive authority. These include VHA Directive 2009–014, *Establishing Medication Prescribing Authority for Clinical Pharmacy Specialists*; VHA Directive 2008–049, *Establishing Medication Prescribing Authority for Advanced Practice Nurses*; VHA Directive 2004–029, *Utilization Of Physician Assistants (PAs)*; and VHA Directive 2008–043, *Scope Of Practice For Pharmacists With Direct Patient Care* (responsibilities).

All practitioners are required to complete the standardized VHA credentialing. Advanced Practice Nurses and Clinical Pharmacy Specialists may be granted either clinical privileges or a Scope of Practice, as determined by their licensure and the facility. Pharmacists with direct patient care responsibilities and Physician Assistants are granted a Scope of Practice.

Question 13: Based on the findings of the Inspector General's June 2009 audit reports, what steps has the VA taken to address issues identified with the management of non-controlled drugs and the CMOP contract?

Response: VHA has taken several steps to address the deficiencies identified in the Office of the Inspector General (OIG) reports. In regard to inventory management, VHA has developed a draft directive outlining the selective monitoring of high cost, high risk non-controlled substances at VA medical centers and it is undergoing review and concurrence to become VHA policy. PBM has communicated all the current dispensing requirements under the draft policy to VA Chiefs of Pharmacy on several conference calls and through e-mail notifications. VA is pursuing Information Technology solutions regarding the use of label reprints and other OIG findings/recommendations and is exploring the ability of its Pharmaceutical Prime Vendor to provide standardized national inventory management tools.

VA's long-term plan to address all of OIG's findings is dependent on the use of enhanced software capabilities to support a comprehensive inventory management system. The specifications for the enhancements were developed and submitted in 2005 to the VA's Office of Information and Technology as part of the Pharmacy Re-Engineering (PRE) project. The current plan is for this functionality to be available sometime in 2011, depending on funding and development priorities.

All CMOP contracting recommendations have been addressed. With the exception of rewriting the CMOP software to improve inventory accountability which is expected to be completed near the end of FY 2010, all proposed actions to meet the OIG recommendations have been completed.

Question 14: Why did the VA allow the directive on Drug Accountability Software to lapse in 2003? Are there plans for an updated directive?

Response: VHA's directive on Drug Accountability was allowed to expire primarily due to the lack of standardized automated national tools to accomplish the requirements. Facilities reported difficulties trying to audit high cost drugs manually. They were unable to accurately reconcile inventories due to dispensing software limitations. It is PBM's belief that a policy which cannot be implemented in the field is not a good management practice; therefore, PBM allowed the directive to expire with the understanding that enhanced software development was due to be implemented in 2008 as part of the PRE project.

After the Drug Accountability policy expired, VA's Chiefs of Pharmacy were advised that although it was no longer in effect, it would be prudent for them to continue some form of drug accountability oversight, using locally developed processes to aid in the detection of diversion of non-controlled substances. PBM recommended that sites take steps to limit the number of storage areas for high cost drugs and reduce inventory levels when possible.

Though VHA still lacks the tools planned for PRE, PBM supports issuing a new directive with monitoring that can be accomplished using currently available tools. A draft policy has been developed and is currently undergoing review for concurrence. Once PRE inventory modules are developed and implemented, VHA will revise the policy to take advantage of the enhanced software capability.